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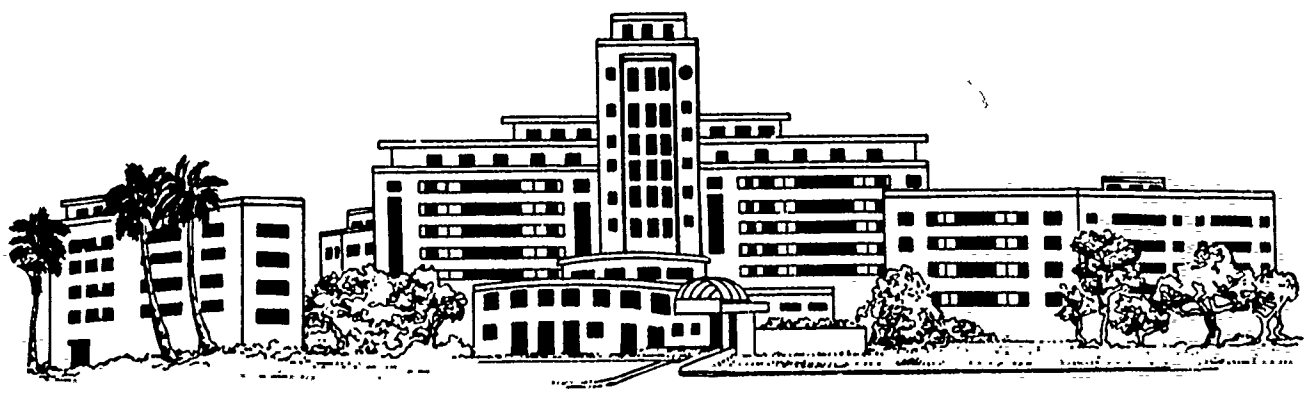

CLINICAL INVESTIGATION PROGRAM

REPORTS CONTROL SYMBOL MED-300 (R1)

FISCAL YEAR 1990

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19. KEY WORDS *(Continue on reverse side if necessary and identify by block number)*

Clinical investigation; experimental projects; research projects; in-house research; publications, presentations of research data; project status; experimental design

20. ABSTRACT *(Continue on reverse side if necessary and identify by block number)*

Subject report identifies those individuals who are conducting investigative protocols at Tripler Army Medical Center. An abstract of each project giving abbreviated technical objectives, methods, and progress is presented.

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A N N U A L P R O G R E S S R E P O R T

DEPARTMENT OF CLINICAL INVESTIGATION
Reports Control Symbol MED-300(R-1)

FISCAL YEAR 1990
1 October 1990

DEPARTMENT OF CLINICAL INVESTIGATION
TRIPLER ARMY MEDICAL CENTER
Tripler AMC, Hawaii 96859-5000

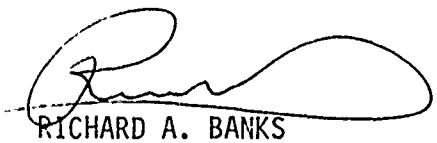
FOREWORD

Fiscal Year 1990 was a very sombering and yet tumultuous period for the Department of Clinical Investigation (DCI) at Tripler AMC. COL Kay A. Kyser, Chief, DCI, valiantly braved an unerringly progressive affliction which reached its culmination in May. Throughout that period, COL Kyser continued to pilot the department as he had previously. He is sorely missed.

However, through the efforts of a staff well-trained and motivated by COL Kyser, Clinical Investigation continued a productive and exciting year. The Joint Neonatal Fellowship between Tripler AMC and Kapiolani Medical Center for Women and Children has flourished and is expanding both physically and into broader areas of research. Dr. John Claybaugh reached the 100th publication mark of his career and continues as an internationally recognized leader in water and electrolyte metabolism. Clinical researchers have continued to expand medical knowledge despite their heavy patient responsibilities. Collaboration in national studies has increased, with Tripler investigators being more involved as principal investigators.

Growth of research at any institution can only be achieved if researchers and clinicians are given the support and encouragement to exercise their thoughts and ideas. COL Kyser provided much of the motivation, but without the vigorous support which Major General Seitter (CG), COL Charles Jones (DCCS), COL Michael Hinton (DCA), Resource Management Division under the guidance of LTC John Heckert and other friends too numerous to mention have given DCI, that motivation would have been useless.

Special thanks also goes to US Army Health Care Studies and Clinical Investigation Activity (HCSCIA) for the guidance and support which they have given so freely during a very rough transition to the new TAMC DCI.



RICHARD A. BANKS
COL, MC
Chief, Department of
Clinical Investigation

DEPARTMENT OF CLINICAL INVESTIGATION
TRIPLER ARMY MEDICAL CENTER

UNIT SUMMARY

A. OBJECTIVES: To sponsor clinical investigation, in compliance with applicable laws, regulations and policies, to increase the academic professional stature of the MEDCEN.

B. TECHNICAL APPROACH: 1) Renew research documentation and advise the Commander and his institutional committees on matters pertaining to clinical investigation, and 2) Provide consultative and collaborative support to approved investigations.

C. STAFFING:

Name	Rank	MOS	Title
Banks, Richard A.	COL	60P9B	Chief
Patterson, Donna L.	MAJ	66E9B	Assistant Chief
Eisenhauer, Carol L.	CPT	64C00	Chief, Animal Research Section
Otto, Christopher	SSG	92B30	NCOIC
Phillips, Geoffrey K.	SSG	01H3R	Biological Science Asst
Anderson, Sandra J.	SGT	91T20	Animal Care Specialist
Johnson, Paula J.	SGT	91T20	Animal Care Specialist
Johnson, Elsa L.	SPC	92B10	Medical Laboratory Specialist
Tostado, Mary D.	SPC	92B10	Medical Laboratory Specialist
Claybaugh, John R.	GM14	00413	Chief, Physiology Section
Mark, Deiren E.****	GS13	01320	Research Biochemist
Sato, Aileen K.	GS11	00644	Medical Technologist
Ichimura, Wayne M.	GS11	00802	Biomedical Engineer
Hashiro, Glenn M.	GS09	00404	Biological Laboratory Tech
Leighnor, Agatha M.	GS07	01087	Editorial Assistant
Parker, Dannell B.	GS05	00318	Secretary (Typing)
Freitas, Brian	WG04	03566	Animal Caretaker
Eichinger, Mark R.*			Biological Laboratory Tech
Griffith, Robert B.*			Biological Laboratory Tech
Dice, Margaret S.**			Biological Laboratory Tech
Yamauchi, Catherine F.T.***			Post Doctoral Fellow

*MRDC Grant (Educational Contract)
**NIH (Educational Contract)
***Leahi Grant (Kapiolani Hospital)
****VA/DOD (Educational Contract)

Officers: 3 authorized; 4 required; 2 assigned
Civilians: 6 authorized; 9 required; 7 assigned
Enlisted: 5 authorized; 7 required; 5 assigned

Number of personnel funded by grants and not included in TDA: 7

D. FUNDING:

Funding Type	1990	SUNY Grant	VA Support Agreement	USMRDC Grant
Civilian personnel including benefits	$271,590.00	$12,000.00	$19,000.00	$21,600.00
Consumable supplies	165,599.00	2,527.14	3,890.36	5,994.20
Civilian contracts including consultants	2,960.00			
TDY	20,239.00	1,173.22	1,292.07	1,287.27
Publications	5,355.34			
OMA Total	460,388.00			
MEDCASE	105,137.00			
Military	323,705.00			
TOTAL	$1,349,618.42	$15,700.36	$24,182.43	$28,881.47

E. PROGRESS:

Number of residency and fellowship training programs that use Clinical Investigation: 14
38 Residents held approved protocols in 1990 with the total number of 42 protocols held by this group in 1990.
4 Fellows held approved protocols in 1990 with the total number of 4 protocols held by this group in 1990.
54 Hospital staff members held approved protocols in 1990 with the total number of 182 protocols held by this group in 1990.

F. PROBLEMS:

Similar to all other military facilities, the onset of hostilities in the Mideast seriously hampered research efforts during the last two months of FY90. A number of presentations had to be cancelled due to a freeze on TDY funding. Equipment and supplies were short during that time, and morale among clinicians and researchers waned. If these factors had not been present, the figures for presentations and publications would have been greater.

History of Tripler Army Medical Center Protocols, Presentations, and Publications

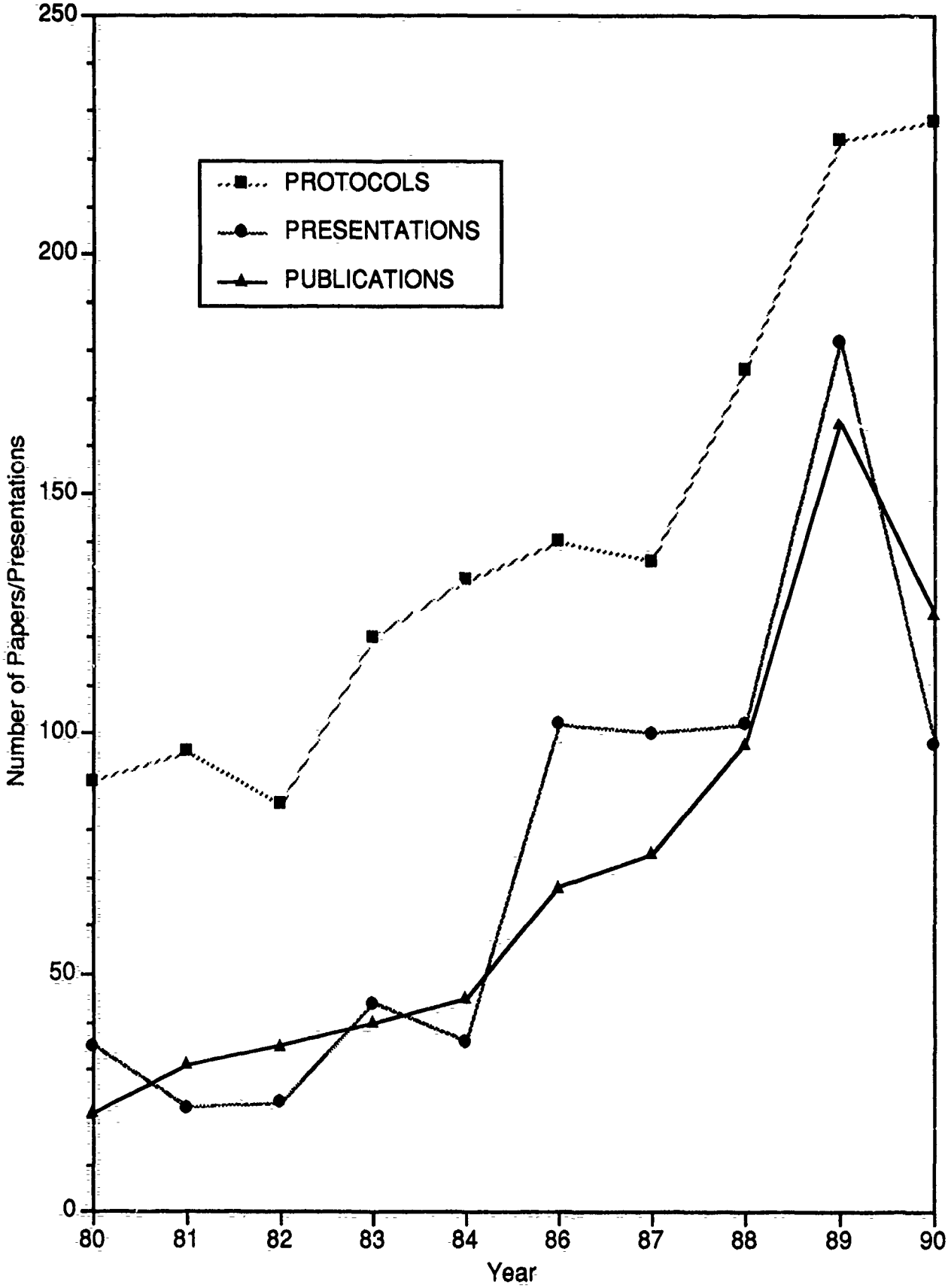


TABLE OF CONTENTS

Code: C - Completed ; O - Ongoing; T - Terminated;
P - Published; PR - Presented; SP - Submitted for Publication

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Fugate D, Foley KT, Fay MJ: Osteotomy of the Coracoid Process for Exposure of the Brachial Plexus. J Bone Joint (SP)

Green MR, Batti'e MC, Bigos SJ: The Role of Acute Back Injury in the Onset of Low Back Problems. J Occup Med (SP)

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Yanklowitz B, Harkless L: Porokeratosis Plantaris Discreta: A Misnomer. J Am Podiatry Medical Assoc, Jul 90

Otolaryngology Service

Antoine GA, Souliere CR, Zieske L, Blumberg A, Yim D: The Advantages of the Rhytidectomy Approach in Surgery of the Parotid Gland. Proc Wash Acad Surg, 1990

Bartels JW, Brammer RE: Cervical Osteomyelitis with Prevertebral Abscess Formation. Otolaryngol Head Neck Surg 120(2):180-182, 1990

Urology Service

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Code: C - Result of an Approved CI Protocol; SP - Submitted for Publication

PRESENTATIONS FY90

DEPARTMENT OF CLINICAL INVESTIGATION

Balaraman V, Kullama LK, Fujiwara N, Sato AK, Nakamura KT: Mechanisms of cGMP Dependent Relaxation to Sodium Nitroprusside and Atriopeptin III in Aorta of Fetal and Adult Guinea Pigs. Society for Pediatric Research Meeting, Anaheim, CA, May 90 (C)

Balaraman V, Kullama LK, Easa D, Robillard JE, Hashiro GM, Nakamura KT: Developmental Changes in Sodium Nitroprusside and Atrial Natriuretic Factor Mediated Relaxation in the Guinea Pig Aorta. Society for Pediatric Research Meeting, Anaheim, CA, May 90 (C)

Claybaugh JR, Uyehara CFT, Sato AK, Letterie GS: Metabolism of Vasopressin by Human Amnion and Amniotic Fluid. Federation of American Societies for Experimental Biology, Washington, DC, Apr 90 (C)

Claybaugh JR, Hong SK, Niu AKC, Goldinger JM, Kwon O, Li M, Lundgren CEG: Theories on the depth-dependent control of body-fluid-regulating hormones to saturation diving. Proceedings of the 10th Meeting of the U.S. Japan Cooperative Program in Natural Resources (UJNR), Kauai, HI, Apr 90

Dice MS, Claybaugh JR: Biphasic Diuresis and Vasopressin Responses in Rats Acutely Exposed to Cold. Federation of American Societies for Experimental Biology, Washington, DC, Apr 90 (C)

Freund BJ, Hashiro GM, Claybaugh JR: Effects of sampling and separation procedures on electrolyte and hormonal concentrations. Federation of American Societies for Experimental Biology, Washington, DC, Apr 90 (C)

Hebden RA, Freund BJ, Claybaugh JR, Ichimura WM, Hashiro GM: Renal, Hormonal and Cardiovascular Responses to Negative Pressure Breathing in Man. Federation of American Societies for Experimental Biology, Washington, DC, Apr 90 (C)

Kullama LK, Balaraman V, Claybaugh JR, Nakamura KT: Development of Sensitivity to Calcium Antagonists in Rat Aorta to KCL, Vasopressin (VP) and Norepinephrine (NE). Federation of American Societies for Experimental Biology, Washington, DC, Apr 90 (C)

Kullama LK, Balaraman V, Pichoff BE, Fujiwara N, Nakamura KT: Ontogeny of Vascular Response to Calcium Antagonists in Rats. Society for Pediatric Research Meeting, Anaheim, CA, May 90 (C)

Krasney JA, Carroll M, Iwamoto J, Claybaugh JR, Hong SK: Renal and Plasma Volume Responses to Atriopeptin (AP) Infusions During Head-out Water Immersion (WI) in Conscious Dogs. Federation of American Societies for Experimental Biology, Washington, DC, Apr 90

Moon RE, Goldinger JM, Claybaugh JR, Niu A, Bennett PB, Hong SK: Diuresis and Nocturia During a Dry Saturation Dive to 46 ATA-GUSI 14. International Group on High Pressure Biology. Toulon, France, Aug 1990 (C)

DEPARTMENT OF DENTISTRY

Bach DE, Boice GW, Finegan F; Newhouse RF: A Quality Assurance Study to Compare Two Treatment Modalities for Mandibular Fractures - An Analysis of Lost Duty Time and Hospitalization Costs to the Military. Association of Military Surgeons of the United States, San Diego, CA, Nov 89

DEPARTMENT OF MEDICINE

Fedalei AG, Sherman K, Seal L, Hamill RL: Evaluation of the Humoral Anamnestic Response to HBsAg in Antibody Negative Hepatitis B Recipients. Hawaii Chapter Scientific Meeting, American College of Physicians, Honolulu, HI, Mar 90

Hassell LH, Olsen J, Moad J: Bronchocentric Granulomatosis Associated with Rapidly Progressive Glomerulonephritis: A Systemic Illness? Hawaii Scientific Meeting, American College of Physicians, Honolulu, HI, Mar 90

Lax D: The Effects of Low Salt Diet on Renal Hemodynamics in the Remnant Kidney Model. American Society of Nephrology Conference, Dec 89

Malinowski TR: Rhabdomyolysis Following Vaccination for Influenza. Hawaii Chapter Scientific Meeting, American College of Physicians, Honolulu, HI, Mar 90

Neeley ET: Eosinophilic Meningitis, A Case Study. 10th Annual AMEDD Neurology Conference, Nov 89

Pfanner TP, Bornemann M: Accelerator Growth of Primary Lymphoma of the Thyroid After Initiating Levothyroxine Therapy. Hawaii Chapter Scientific Meeting, American College of Physicians, Honolulu, HI, Mar 90

Prager DA, Hassell LH, Claybaugh JR: Suppression of Polydipsia with Captopril in a Hyperreninemic Patient: Evidence for Angiotensin II as a Potent Dipsogen. American College of Physicians Annual Session, Chicago, IL, Apr 90

Stoll B, Bornemann M: Graves Disease Masquerading as Right Heart Failure in a Young Man. Hawaii Chapter Scientific Meeting, American College of Physicians, Honolulu, HI, Mar 90

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Bork MD, Gold JA, Kopelman JN, Miyazawa K: Congenital Eventration of the Right Hemidiaphragm Complicating Pregnancy. ACOG, Washington, DC, Nov 89

Bruner JP, Forouzan I: The acute effect of smoking and buccally-administered nicotine on uterine and umbilical artery doppler flow velocity waveforms. ACOG, Washington, DC, Nov 89

Bruner JP, Landon MB, Ludmir J, Gabbe SG: Doppler Ultrasonography in Pregnancies Complicated by Insulin-Dependent Diabetes Mellitus and Vasculopathy. ACOG, Washington, DC, Nov 89

Hubbard JE, Bruner JP, Kopelman JN, Miyazawa K: Universal Maternal Serum Alpha Fetoprotein Screening--the Tripler experience. ACOG, Washington, DC, Nov 89

Letterie GS, Ramirez EJ, Miyazawa K: Serum Human Chorionic Gonadotropin (hCG) Surveillance after Radical and Conservative Management of Ectopic Pregnancy (EP). ACOG, Washington, DC, Nov 89 (C)

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Mandel RI, Bruner JP, Miyazawa K: Endocardial fibroelastosis: An Unusual Cause of Pulmonary Hypertension in Pregnancy. ACOG, Washington, DC, Nov 89

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McNulty K, Miyazawa K: Urologic Injuries Encountered During Abdominal and Vaginal Hysterectomy. ACOG, Washington, DC, Nov 89

Moorman AJ, Miyazawa K, Bruner JP: Fetal Supraventricular Tachycardia Successfully Treated with Maternal Digitalization. ACOG, Washington, DC, Nov 89

Shen-Gunther J, Kopelman J, Miyazawa K: Amniofusion Quantified by Amniotic Fluid Index Assessments: Preliminary Findings. ACOG, Washington, DC, Nov 89 (C)

Shen-Gunther J, Miyazawa K: Epidemiological Observations and Pathologic Findings of Cervical Conization: The Tripler Experience. ACOG, Washington, DC, Nov 89

Shen-Gunther J, Andrews S, Miyazawa K: Primary Peritoneal Carcinomatosis: Report of Two Cases and Review of the Literature. ACOG, Washington, DC, Nov 89

Vogel EJ, Shen-Gunther J, Hibbert M, Miyazawa K: Ovarian Pregnancy in a Copper T IUD User. American College of Obstetrics and Gynecologists and the Organization for Obstetric, Gynecologic and Neonatal Nurses, Washington, DC, Nov 89

DEPARTMENT OF PATHOLOGY AND AREA LABORATORY SERVICES

Trant CM: Insects is Insects. American Academy of Forensic Sciences, Cincinnati, OH, Oct 90

DEPARTMENT OF PEDIATRICS

Pichoff BE II, Schydlower M, Stephenson SR: Military dependent children at risk for accidental hot tap water burns. American Academy of Pediatrics, Chicago, IL, Oct 89

Southgate WM, Pichoff BE, Balaraman V, Kullama LK, Uemura HS, Nakamura KT: Age Variable Effects of Epithelium Removal on Guinea Pig Airway Smooth Muscle Response to Acetylcholine and Histamine. Society for Pediatric Research Meeting, Anaheim, CA, May 90 (C)

Stevens EL, Venkataraman BW, Southgate M, Nakamura KT: Ontogeny of Sodium Nitroprusside and Atriopeptin III Relaxation in Guinea Pig Airway Smooth Muscle. Society for Pediatric Research, Anaheim, CA, May 90 (C)

PHARMACY SERVICE

Diehl LD, Goo EDH, Sumlye L, Ferrell RJ: Sterile Products Service Waste Management. American Society of Hospital Pharmacy (ASHP), Las Vegas, NV, Dec 90

DEPARTMENT OF RADIOLOGY

Fellows DW, Haggerty M, Mulligan M, Hansen M: Diagnostic Accuracy of Teleradiology Between Johnston Atoll and Tripler Army Medical Center. 38th Parallel Medical Conference, Seoul, Korea, Nov 89

Logsdon GA: Deep Venous Thrombosis of the Lower Extremity Detection by Ultrasonography. 38th Parallel Medical Conference, Seoul, Korea, Nov 89

DEPARTMENT OF SURGERY

General Surgery Service

Chapman WH, Shim WKT, Barcia PJ: Femoral hernias in children. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Chapman WH, Shim WKT, Barcia PJ: Postoperative intussusception in infants and children. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Dixon JW, Martin R, Lee YTM: Extrahepatic bile duct injury from blunt abdominal trauma. 38th Parallel Medical Conference, Seoul, Korea, Nov 89

Dixon JW, Lisehora GB, Lee YTM: Common bile duct carcinoid tumor. 38th Parallel Medical Conference, Seoul, Korea, Nov 89

Dixon J, Runke L, Gore N: Anti-mediator therapy in septic shock: Treatment choice or chemical last rights. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Dixon JW, Martin R, Lee YTM: Extrahepatic bile duct injury from blunt abdominal trauma. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Fengler SA, Limm W, Lee MYT: Leimyosarcoma of the colon and rectum: A review of seventeen cases. Gary P Wratten Surgical Symposium Rockville, MD, Apr 90

Fengler SA, Barcia PJ: Urgent preoperative preparation of a patient with pheochromocytoma. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Johnson EA: The Impossible Airway: A Radical New Approach. 38th Parallel Medical Conference, Seoul, Korea, Nov 89

Johnson EA: Common adult anorectal disease. 38th Parallel Medical Conference, Seoul, Korea, Nov 89

Knuth TE, Lee MYT: Acute cholecystitis in the aids patient. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

McDonnell BE, Huang YC, Barcia PJ: Torsion of the normal ovary in prepubescent women: A diagnostic dilemma. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Meade PG, Raines KB, Lee MYT: Hyperparathyroidism: surgical experience at Tripler Army Medical Center. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Morey AF, Foley HT, McLead DG, Pendergrass TL: Malpractice claims for urogenital injuries. 38th Parallel Medical Conference, Seoul, Korea, Nov 89

Murray L, Rudolph C, Barcia PJ, Leutkehans T, Logsdon G: The role of ultrasonography in the diagnosis of acute appendicitis. 38th Parallel Medical Conference, Seoul, Korea, Nov 89

Murray L, Huang YC: Congenital polysplenia syndrome and associated anomalies. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Murray L, Huang YC: Total gastrectomy with survival in an infant. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Napoli PJ, Larson A: Contained traumatic rupture of the thoracic aorta. 38th Parallel Medical Conference, Seoul, Korea, Nov 89

Roth BJ, Lee MYT: Intestinal duplications: A Case Report and Review of the Literature. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Scorza LB, Johnson EA: Toxic epidermal necrolysis -- what the surgeon should know. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Sheridan MF, Murray L, Barcia PJ: Evisceration of omentum as an unusual complication of inguinal herniorrhaphy. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Tieva M, Barcia PJ: Hepatic dysfunction mimicking adrenal feminizing tumor: A Case Report and review of the literature. Gary P Wratten Surgical Symposium, Rockville, MD, Apr 90

Orthopedic Service

Albertson KS: Periosteally Vascularized Autograft for the Augmentation of Allograft. Combined Spring Orthopaedic Symposium, Kahuku, HI, Jun 90

Bendowski TF: Analysis of Factors Influencing Rate of Re-operation in 147 Clubfeet. Society of Military Orthopaedic Surgeons Meeting, San Antonio, TX, Dec 89

Christensen KP, Powell JN: Early Results of a New Technique for the Treatment of High Grade Tibial Plateau Fractures. Meeting of Orthopaedic Trauma Association, Philadelphia, PA, Oct 89. Combined Spring Orthopaedic Symposium, Kahuku, HI, Jun 90. Canadian Orthopaedic Association Meeting, Jun 90

Christensen KP: Orthopaedic Surgical Wound Experiences. Soft Tissue Surgery Workshop, Jan 90

Cirillo RM, Quinlan EC: An Unusual Presentation of an Active Enchondroma of the Femoral Head and Neck in Adults. Combined Spring Orthopaedic Symposium, Kahuku, HI, Jun 90

Davis SS: Pigmented Villonodular Synovitis of the Radio-ulnar Joint: A Case Report and Literature Review. Combined Spring Orthopaedic Symposium, Kahuku, HI, Jun 90

Drinhaus RR: Calcaneal Fractures in Children-CT Assessment and Literature Review. Combined Spring Orthopaedic Symposium, Kahuku, HI, Jun 90

Eline EA: Transverse Myelitis: Orthopaedic Presentations: A Review of the Literature and Case Report. Combined Spring Orthopaedic Symposium, Kahuku, HI, Jun 90

Fugate DS, Foley KT, Fay MJ: Osteotomy of the Coracoid Process for Evaluation of the Distal Brachial Plexus. American Academy of Orthopedic Surgeons Meeting, Anaheim, CA, Mar 90. Combined Spring Orthopaedic Symposium, Kahuku, HI, Jun 90 (C) (SP)

Jackson JM: Management of Skeletal Defects by the Ilizarov Intercalary Bone Transport Method. Combined Spring Orthopaedic Symposium, Kahuku, HI, Jun 90

Moore RK: Early Experience with Reamed Locked Humeral Nails. Combined Spring Orthopaedic Symposium, Kahuku, HI, Jun 90

Pitcher JD, Jones D: Sixty-five Years Experience with Pin Fixation in Children. Combined Spring Orthopaedic Symposium, Jun 90. Society of Military Orthopaedic Surgeons Meeting, San Antonio, TX, Dec 89

Pitcher JD: Primary Benign Intraosseous Lesions of the Sacrum: Clinical Aspects. American Academy of Orthopaedic Surgeons, Anaheim, CA, Mar 90

Reesor KE, Douglas GL, Jones DA: Intrapelvic limb equalization. Society of Military Orthopaedic Surgeons Meeting, San Antonio, TX, Dec 89

Rungee JL, Reinker KA: Ossific Nucleus Eccentricity in Congenital Dislocation of the Hip. Combined Spring Orthopedic Symposium, Kahuku, HI Jun 90. Orthopedic Resident's Conference, Memphis, TN, Aug 90

Rungee JL, Fay MJ, DeBerardino TM: Biomechanical Implications of Olecranization on the Patella. Orthopedic Resident's Conference, Memphis, TN, Aug 90 (C) (SP)

Smith T: The Use of Absorbable (Poly-p-dioxanone) Pins Versus Kirschner Wires for Internal Fixation of Chevron Osteotomies for Hallus Valgus. DOD Podiatry Conference, Presidio-San Francisco, CA, Jun 90. Shogun Medical Society Symposium, Tokyo, Japan, May 90 (C)

Thomson JD: Fractures of the Distal Femoral Epiphysis. Society of Military Orthopedic Surgeons, Dec 89. Combined Spring Orthopaedic Symposium, Kahuku, HI, Jun 90

Yanklowitz B, Romash MM, Fugate D: Passive Range of Motion of the First Metatarsal Cuneiform Joint-Preoperative Assessment. DOD Podiatry Conference, Presidio-San Francisco, CA, Jun 90

Otolaryngology Service

Bartels JW, Burgess LP, Edmond C: Adenoid Cystic Carcinoma with Intracranial Metastasis. American Academy of Otolaryngology-Head and Neck Surgery, San Diego, CA, Sep 90

Mahoney EM, Zieske LA, Lunde KC: Nasal Parapharyngeal Juvenile Angiofibroma Excised Via a Combined Cervical - Trans and Lateral Antral Surgical Approach. American Academy of Otolaryngology-Head and Neck Surgery, San Diego, CA, Sep 90

Mahoney EM, Zieske LA: Chronic Fungal Sinusitis: Characteristics in Tissue and Classification of Causative Organisms. American Academy of Otolaryngology-Head and Neck Surgery, San Diego, CA, Sep 90

Tomaski SM, Souliere CR: Deep Parotid Hemangioma Presenting as an Intraoral Mass. American Academy of Otolaryngology-Head and Neck Surgery, San Diego, CA, Sep 90

Tomaski SM, Yim DWS: Intracranial Complications of Otitic Origin in Pacific Island Children. American Academy of Otolaryngology-Head and Neck Surgery, San Diego, CA, Sep 90

Yim DWS, Van Sant TE, Burgess LPA: The External (Combination) Rhinoplasty Approach: Access for Management of the Problem Nasal Deformity. American Academy of Otolaryngology-Head and Neck Surgery, San Diego, CA, Sep 90

Zieske LA, Yim DWS: Open Rhinoplasty Approach for Transseptal Sphenoid Sinus and Transsphenoidal Surgery. North American Skull Base Society, Los Angeles, CA, Feb 90. American Academy of Otolaryngology-Head and Neck Surgery, San Diego, CA, Sep 90

Urology Service

Allen RC, Wikert GA, Dresner ML: Prostatic Abscess. 37th Kimbrough Urology Seminar, San Antonio, TX, Dec 89.

Crain TW, Runke LC, Kennon WG: Acute Urinary Retention Following Inguinal Hernia Repair. 37th Kimbrough Urology Seminar, San Antonio, TX, Dec 89.

Desmond PM, Wikert GA: Single Nephrostomy Treatment of Staghorn Calculi. 37th Kimbrough Urology Seminar, San Antonio, TX, Dec 89.

Dresner ML: Utility of the Endoscopic Video Camera in Urology Residency Training. 37th Kimbrough Urology Seminar, San Antonio, TX, Dec 89.

Kennon WG: Long Term Follow-Up in the Military: A Guide to Finding the "Lost" Patient. 37th Kimbrough Urology Seminar, San Antonio, TX, Dec 89.

Morey AF, Wikert GA, Kennon WG, Dresner ML: Fertility Issues in the Therapy of Early Stage Seminoma. 37th Kimbrough Urology Seminar, San Antonio, TX, Dec 89.

Wikert GA: Intrahepatic Applications of Endourology. 37th Kimbrough Urology Seminar, San Antonio, TX, Dec 89.

Code: C - Result of an Approved CI Protocol; SP - Submitted for Publication

Detail Summary Sheet

Prot No: 1A88 Status: Ongoing

TITLE: Effects of Des-leu Angiotensin I, Cortisol, and Hyperbaria on the Release of Vasopressin from the Isolated Hypothalamoneurohypophyseal System

Principal Investigator: John R. Claybaugh, Ph.D.
Associate Investigators: Aileen K. Sato, Med Tech;
Glenn M. Hashiro, Bio Lab Tech.;
David G. Changaris, MD; Suk Ki Hong, MD, Ph.D.;
Wayne Ichimura, Biomedical Engineer

Department/Section: Clinical Investigation/Physiology

Key Words: des-leu angiotensin I

Funding: FY 89: $19,481 FY 90: $24,604 Periodic Review Date: Sep 90
Gifts: VA-DOD Grant Decision: Continue

OBJECTIVE: 1) To determine if des-leu angiotensin I is able to stimulate vasopressin from the isolated hypothalamoneurohypophyseal system (HNS) in a manner similar to angiotensin II. 2) To determine if cortisol can inhibit baseline or stimulated vasopressin release from the HNS. 3) To determine if hyperbaria will inhibit the release of vasopressin from the HNS. To determine if des-leu angiotensin I stimulates vasopressin release in conscious goats and the control mechanism of the response.

TECHNICAL APPROACH: Two approaches to isolated hypothalamoneurohypophyseal explants have been followed, a tissue incubation (acute) and a tissue culture (chronic) approach. Both involve the surgical removal of the floor of the brain of the rat, a triangular piece of tissue approximately 1 mm thick, with a base extending parallel and anterior to the optic chiasma, and the apex approximately 2 mm posterior to the stalk of the neurohypophysis. The anterior pituitary is removed. The resulting tissue block includes the supraoptic nucleus with intact axonal projections through the stalk to the neurohypophysis. We have also begun studies on the central (intracerebroventricular) administration of angiotensin II and des-leu angiotensin I.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Acute rat HNS preparations exposed to 10-100 uM angiotensin II (AII) exhibited an increased dose-dependent release of vasopressin (AVP) over basal levels. Media osmolality of 500 mOsm/kg also significantly increased AVP release. Anesthesia prior to decapitation lowered the basal release rate of the HNS prep. In addition, the acute rat HNS prep may not be sensitive to des-leu angiotensin I. Experiments done to determine the response of the pituitary alone found the basal release was lower in the pituitary prep but AII-stimulated increments were similar to the HNS response. Osmotic stimulation was more dependent on the hypothalamus. An adjustable pressure chamber (up to 2000 psi) for the HNS was developed; preliminary data indicates that hyperbaria may affect the HNS release of AVP. Experiments with conscious goats failed to progress due to a lack of better stereo-taxic equipment (ordered and waiting for delivery).

Detail Summary Sheet

Prot No: 11A87	Status: Ongoing
TITLE: The Metabolic Clearance of Arginine Vasopressin in the Amniotic Sac	
Principal Investigator: John R. Claybaugh, Ph.D. Associate Investigators: Catherine F. T. Uyehara, Ph.D.; Aileen K. Sato, Med Tech	
Department/Section: Clinical Investigation/Physiology	
Key Words: arginine vasopressin;	
Funding: FY 89: $264 FY 90: $5,381 Gifts: None	Periodic Review Date: Sep 90 Decision: Continue

OBJECTIVE: To demonstrate that the amniotic sac is a major site of fetal AVP clearance. Further, we will determine where in the amniotic sac AVP metabolism occurs (via amniotic fluid enzymes and/or via amnionic membrane receptors), explore the kinetics of this metabolic process, and characterize the metabolites produced.

TECHNICAL APPROACH: Vasopressin, either unlabelled or labelled with tritium is incubated with amniotic fluid, amnionic membrane, or other known vasopressin-metabolizing enzymes and chemicals (eg. vasopressinase of pregnancy serum, trypsin, thioglycolate) for biochemical identification of metabolic products. The metabolites will be characterized by their HPLC elution profiles. Guinea pig amniotic sac metabolites will be compared with metabolites produced by human amniotic fluid and amnion to determine whether the amniotic sac provides a route for fetal vasopressin clearance in humans as well.

PROGRESS: No. of Subjects Enrolled - To Date: NA
Reporting Period: 1989-1990

HPLC characterization of metabolites is ongoing. One metabolite produced by both guinea pig and human amniotic fluid has been verified to be desglycinamide vasopressin and co-migrates with the metabolic product produced after vasopressin incubation with trypsin. Another as yet unidentified metabolite produced after incubation with both guinea pig and human amnionic membrane is possibly a product similar to that produced after pregnancy serum vasopressinase metabolism.

Detail Summary Sheet

Prot No: 20A88 Status: Completed

TITLE: Stop-flow Analysis of Sodium Entry and Tubular Transit Times for Sodium and Inulin in Normal and Nephrotic Rats

Principal Investigator: John R. Claybaugh, Ph.D.
Associate Investigators: Aileen K. Sato, Med Tech

Department/Section: Clinical Investigation/Physiology

Key Words: vasopressin (ADH);

Funding: FY 89: $1,824 FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: The purpose of the proposed experiments is to extend our current investigations on the effects of atrial natriuretic peptides (ANP) on sodium transport in kidneys as follows: (1) To use "stop-flow" analysis in an attempt to locate the tubular level at which extra-luminal sodium enters the nephron. (2) To measure the effects of ANP on simultaneous indicator dilution curves for sodium and inulin in a rat model of an ANP-resistant salt and water retaining state (Adriamycin nephrosis) using innervated or denervated kidneys.

TECHNICAL APPROACH: Because of 22-Na disposal problems possibly occurring, the more difficult approach utilizing an isolated kidney was developed. The first steps in validating the function of the kidney included the clearance of creatinine, Na, and K, and the determination of effects of vasopressin and its clearance. This has yielded interesting results regarding vasopressin clearance which we are presently pursuing before continuing on to the original sodium handling questions we were after.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Progress (through August 88): To date we have successfully developed an isolated perfused rat kidney preparation that is physiologically functional for a period of about two hours. This is in agreement with previous publications. We have established that these kidneys are responsive to vasopressin in that they produce a more concentrated urine when vasopressin is in the media. We have also determined that vasopressin is metabolized by at least two mechanisms in this preparation. First via filtration and excretion, but approximately 10 fold more via other renal mechanisms presumably in the vasculature. When a V_2 vasopressin antagonist was added to the medium, the peritubular clearance of vasopressin was inhibited by 75%, but the urinary clearance was not significantly affected.
Keeler R, Sato AK, Claybaugh JR: Effect of V_2 antagonist on the Clearance of vasopressin by Isolated Perfused Rat Kidneys. FASEB J 3:A246, 1989 (Abs #112).

This protocol has now been completed and the manuscript is now in preparation.

Detail Summary Sheet

Prot No: 21A89 Status: Ongoing

TITLE: Effects of Hypoxia on the Vasopressin Response to Hemorrhage and its Role in the Maintenance on Blood Pressure

Principal Investigator: John R. Claybaugh, Ph.D.
Associate Investigators: Mark R. Eichinger, Graduate Assistant

Department/Section: Clinical Investigation/Physiology

Key Words: hypoxia; vasopressin;

Funding: FY 89: $7,911 FY 89: $33,453 Periodic Review Date: Sep 90
Gifts: MRDC Grant Decision: Continue

OBJECTIVE: There is reason to believe that the maintenance of basal blood pressure and blood pressure in response to hemorrhage would be altered during conditions of hypoxemia. Similarly, pulmonary arterial blood pressure is altered during hypoxia. We propose to determine if an altered vasopressin response or vascular responsiveness is in part responsible. In addition to volume control, osmotic control of vasopressin may be altered during hypoxia. This too, will be investigated.

TECHNICAL APPROACH: We have chosen the conscious adult goat as our animal model. All animals to be employed in the study must first undergo surgical procedures for the construction of a carotid artery loop and tracheal fistula. The carotid artery loop allows for both blood sampling and the means of blood withdrawal during the hemorrhage studies. The fistula is used to make the animal hypoxemic by introduction of nitrogen through a tracheal catheter. The level of hypoxemia is determined through blood gas analysis, and radioimmunoassays are employed for measurement of hormonal changes.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

To date, six goats are actively involved in protocol 21A89. Final details of the hypoxemic gas administration as well as the hemorrhage procedure have been worked out. Four goats have participated in both the normoxic and hypoxic control experiments; in addition, three goats have participated in both the hypoxic and normoxic hemorrhages. It appears that indeed there is a difference in the cardiovascular and hormonal responses to the two forms of hemorrhage. These findings are encouraging and work is in full progress.

Detail Summary Sheet

Prot No: 36A89 Status: Completed

TITLE: Ontogeny of the Mechanisms of Arginine Vasopressin and Vasotocin Mediated Contraction

Principal Investigator: John R. Claybaugh, PhD
Associate Investigators: Linda K. Kullama, PhD; Dr. Kenneth T. Nakamura, MD; Dr. Venkataraman Balaraman, MD; Wayne M. Ichimura, Biomed Engineer

Department/Section: Clinical Investigation/Physiology Service

Key Words: arginine vasopressin; vasotocin;

Funding: FY 89: $15,104 FY 90: $6,428 Periodic Review Date: Sep 90
Gifts: grant* Decision: Completed

OBJECTIVE: To define the ontogeny of the mechanism(s) of arginine vasopressin (AVP) and arginine vasotocin (AVT) mediated contraction as compared to norephinephrine (NE) mediated contraction.

TECHNICAL APPROACH: We are using invitro isometric tension measurements of the contractile response of rings of rat thoracic aorta in the presence and absence of Ca blockers and Ca-free solutions. We will be utilizing __ Ca in in vitro experiments using similar composition solutions - this portion has not been started yet.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Results indicate that for the categories of calcium channel antagonists that interact at the phenylalkylamine (verapamil) and benzothiazepine (diltiazem) binding sites, there were age-related increases in effectiveness for blocking both POC and ROC. However, for nifedipine, which binds to the 1, 4-dihydropyridine binding site, no maturational change was observed.

ABSTRACTS: 1) Kullama, L.K.; Balaraman. V.; Claybaugh, J.R.; Nakamura, K.T.: Development of sensitivity to calcium antagonist in 1 at aorta to KCI, vasopressin and norepinephrine, FASEB J: A 269, 1990.
2) Kullama, L. K.; Balaraman, V.; Pichoff, B.E.; Fujiwara, N.; Nakamura, K.T.: Ontogeny of vascular response to calcium antagonists in rats. Pediatric Res 27: 234A, 1990.

PRESENTATIONS: 1) FASEB meetings, April 2, 1990, Washington, D.C., (Platform Presentation).
2) Society for Pediatric Research, May 9, 1990, Anaheim, CA (Platform Presentation)

MANUSCRIPT IN PRESS: Kullama, L.K.; Balaraman, V.; Claybaugh, J.R.; Ichimura, W.M.; Pichoff, B.E.; Nakamura, K.T.: Differential ontogeny of in vitro vascular responses to three categories of calcium channel antagonists in rats.

* American Heart Association Fellowship Grant

Detail Summary Sheet

Prot No: 41A86 Status: Completed

TITLE: Effects of Elevated Mineralocorticoid on Blood Pressure, Thirst, and Vasopressin Responses to Angiotensin in the Goat

Principal Investigator: John R. Claybaugh, Ph.D.
Associate Investigators: CPT Beau J. Freund, MS; Aileen K. Sato, Med Tech; MAJ Albert H. McCullen, VC

Department/Section: Clinical Investigation/Physiology

Key Words: mineralocorticoid; vasopressin; angiotensin;

Funding: FY 89: $23,272 FY 90: $20,077 Periodic Review Date: Sep 90
Gifts: VA/DOD Grant Awarded Decision: Completed

OBJECTIVE: To determine if the vasopressin (VP) response to angiotensin II is enhanced by previous administration of aldosterone, and whether the VP responses to central or peripheral administration of angiotensin II are differentially affected by the aldosterone treatment.

TECHNICAL APPROACH: Goats will be surgically prepared with chronic and indwelling cannula in the lateral ventricle of the brain and a carotid arterial loop. After two weeks of aldosterone or vehicle injections, the responsiveness to angiotensin II will be determined. The angiotensin will be administered IV or into the lateral ventricle of the brain. The blood pressure, thirst, and CSF and plasma ADH responses will be determined.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Prior administration of mineralocorticoid (DOCA), as expected reduces resting levels of plasma renin activity (PRA). We also observed a significant increase in atrial natriuretic factor (ANF). Peripheral iv administration of angiotensin II (n=6) significantly reduced PRA, and increased ANF, vasopressin, and blood pressure in goats with and without prior DOCA administration. Prior DOCA administration increased the blood pressure response and reduced the vasopressin response to iv angiotensin II. Intracerebroventricular angiotensin II stimulated vasopressin, and increased blood pressure and decreased ANF (n=4), but no differences in these responses appears to be affected by prior administration of DOCA. Samples have been set aside for ACTH analysis. Consistent with previous reports, prior DOCA administration does appear to "up-regulate" angiotensin II receptors in the vasculature since AII produced a greater increase in blood pressure after DOCA administration. However, we found no "up regulation" of centrally mediated AII response or peripheral AII effects on hormones. Publication: Claybaugh JR, Sato AK, Freund BJ, McCullen AH: Effects of Prior Mineralocorticoid (DOCA) Administration on ADH Responses Intracerebroventricular (ivt) or iv Angiotensin II. FASEB J 3:A246, 1989 (Abs #113).

This protocol has now been completed and the manuscript is in preparation.

Detail Summary Sheet

Prot No: 52A89 Status: Ongoing

TITLE: Effects of Vasopressin on Pulmonary Vascular Resistance in Hypoxia Induced Pulmonary Arterial Hypertension in Newborn and Adult Pigs

Principal Investigator: John R. Claybaugh, Ph.D.
Associate Investigators: David Easa, MD; Catherine F.T.Uyehara, Ph.D.
Kenneth T. Nakamura, MD; Mark Eichinger;
Aileen K. Sato

Department/Section: Clinical Investigation/Physiology Section

Key Words: vasopressin; hypoxia;

Funding: FY 89: FY 90: $9,089 Periodic Review Date: Sep 90
Gifts: $30,000. Leahi Trust Decision: Continue

OBJECTIVE: To determine the vasopressin response of the pig to acute hypoxic exposure (i.e. 10% inspired O_2) and characterize this response in pigs of ages ranging from newborn to 3 months. We will also assess the atrial natriuretic peptide responses in the same series. To determine the pulmonary arterial pressure and pulmonary vascular resistance (PVR) response of the newborn pig to hypoxia. To determine the pulmonary arterial pressure and PVR responses to vasopressin or atrial natriuretic peptide of the pig. To determine the sensitivity of the hypoxia induced pulmonary arterial hypertension and PVR to V1 and V2 receptor blockade. In addition, the effect of negative pressure respiration on the hypoxic increase in pulmonary vascular resistance will be examined.

TECHNICAL APPROACH: Five- thru ten-day old piglets are instrumented with cardiac catheters for measurement of mean arterial pressure, right atrial pressure, pulmonary artery pressure, left ventricular pressure and cardiac output by thermodilution. Femoral artery and vein catheters are placed for blood sampling and infusions. An endotracheal tube is placed for monitoring ventilation and administration of hypoxic gas.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period: 4/90-10/90

Start of project was delayed until mid April 1990 (awaiting approval from the Secretary of the Army and receipt of the Leahi Trust Grant). In the last few months the animal model has been well established with all catheterization techniques and cardiac and respiratory measurements in place. Currently, other publications in the literature have employed the use of piglets of an average age of 18 days for experiments using Swan-Ganz catheterization. We have been able to work with piglets as young as three days old and found that the minimum body weight required to achieve consistent placement of the Swan-Ganz catheters is 2.0 kg. The model allows reproducible tolerance to 15% hypoxia. We have conducted experiments on 30 piglets to date, and have been able to observe responses as follows: (1-3) 15% hypoxia increases PAP, CO, PVR; (4) no shunting of blood observed after hypoxia; (5-6) 15% hypoxia increases plasma vasopressin levels and decreases plasma aldosterone levels; (7) negative pressure does not improve PVR but does improve blood gases.

Detail Summary Sheet

Prot No: 54H89* Status: Completed

TITLE: Responses of Water and Electrolyte Regulating Hormones During a Saturation Dive to 450M

Principal Investigator: John R. Claybaugh, Ph.D.
Associate Investigators: Peter B. Bennett, Ph.D.; Richard E. Moon, MD; Suk Ki Hong, MD, Ph.D.; James Goldinger, Ph.D.

Department/Section: Clinical Investigation/Physiology Section

Key Words: electrolyte;

Funding: FY 89: $705 FY 90: Periodic Review Date: Sep 90
Gifts: NIH Decision: Completed

OBJECTIVE: Document diuresis in Trimix 450 M dive and to determine whether there is an alteration in the circadian pattern of urine flow and/or excretion of electrolytes. To determine if hormones that regulate the volume and excretion of osmotic particles, sodium, and potassium in urine are altered in this environment.

TECHNICAL APPROACH: There will be 4 subjects, all male professional saturation divers. We will collect all urine and 11 blood samples each. The dive schedule will include 2 days predive, 7 days at 450M, 4 days decompression and 4 days at 360M, 4 days decompression and two days decompression to 265M then 12 days decompression to sea level and 2 days post control. The study will begin September 30, 1989 and end November 8, 1989.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Study completed November 8, 1989. Upon return to U.S., and putting samples in freezer the same day, the freezer failed and all plasma hormone analyses were lost. We were able to salvage only urinary vasopressin and aldosterone analyses. We were able to determine that hyperbaria equivalent to 450 M in a TRIMIX environment causes diuresis, most profound at night, characterized by a natriuresis, an increase in osmotic excretion and a free water excretion. These results were reported in abstract form (see below). The hormone analysis is complete, but statistics and data interpretation are currently underway. We will be returning to Germany in 1990 to conduct another experiment in which most of the lost data can be recouped.

ABSTRACTS: 1) Goldinger, J.M.; Claybaugh, J.R.; Niu, A.; Moon, R.E.; Bennett, P.B.; and Hong, S.K. Diuresis and Nocturia during a dry saturation dive to 46 ATA - GUSI 14. International group on high pressure biology. Toulon, 19 - 22, August, 1990.
2) Moon, R.E.; Exposito, A.J.; Compresi, E.M.; Fawcett, T.A.; Claybaugh, J.R.; Goldinger, J.M.; Hong, S.K.; Bennett, P.B.; and Holthaus, J.: Prevalence of thrombocytopenia in deep saturation diving. Joint Meeting on Diving and Hyperbaric Medicine. (Abstract) 1990.
3) Moon, R.E.; Fawcett, T.A.; Exposito, A.J.; Claybaugh, J.R.; Goldinger, J.M.; Hong, S.K.; Bennett, P.B.; and Holthaus, J. Plasma volume measurement during deep saturation dive. Joint Meeting on Diving and Hyperbaric Medicine (Abstract 1990).
*Exempt from committee protocol.

Detail Summary Sheet

Prot No: 56A89 Status: Ongoing

TITLE: Mechanism of Cold Induced Diuresis

Principal Investigator: Margaret S. Dice
Associate Investigators: John R. Claybaugh, Ph.D.; Aileen K. Sato; Wayne M. Ichimura; CPT Beau J. Freund, MS

Department/Section: Clinical Investigation/Physiology Section

Key Words: cold diuresis;

Funding: FY 89: FY 90: $5,952 Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: This study will attempt to clarify the hormonal determinants of cold diuresis. Specifically, the study will test the "Gauer-Henry hypothesis" whereby central blood volume expansion is proposed to increase water and sodium excretion. In addition experiments will be conducted to evaluate the role of the "Gauer-Henry" hypothesis in the onset and continuance of the cold diuresis.

TECHNICAL APPROACH: To evaluate the diuretic response of conscious rats to low ambient temperatures - blood pressure, relevant blood and urinary hormones, and urine flows will be measured via indwelling catheters. Bilateral cervical vagotomy will be performed to determine the contribution of cardiac low pressure receptors to the diuresis.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Vasopressin has been re-evaluated during narrower time intervals than used previously, giving a more detailed picture of the time course of hormonal changes. Right atrial pressure responses to cold exposure have been measured and found to increase.

Detail Summary Sheet

Prot No: 39H88 Status: Completed

TITLE: Hormonal and Renal Responses to Exercise: Effects of Exercise

Principal Investigator: CPT Beau J. Freund, MS
Associate Investigators: Everett M. Shizuru, Graduate Student; John R. Claybaugh, Ph.D.; MAJ Thomas A. Perkins, MC; Glenn Hashiro, M.S.

Department/Section: Clinical Investigation/Biochemistry

Key Words: hormonal and renal responses;

Funding: FY 89: $7,075. FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: The purpose of this study will be to: 1) investigate the effects of exercise intensity on renal function; 2) determine the mechanisms responsible for the diuresis and natriuresis reported during Tow intensity exercise; 3) to investigate the stimuli responsible for the release of atrial natriuretic peptide (ANP).

TECHNICAL APPROACH: Subjects: Eight to twelve healthy male subjects of varying fitness states and between the ages of 20 and 39 years will be recruited for this study. The methodology and experimental protocol will be explained in detail to all prospective subjects with written informed consent being obtained prior to data collection. In addition, all subjects will be informed that they may withdraw at any time form the study without ill will.

PROGRESS: No. of Subjects Enrolled - To Date: 8 Reporting Period: 8

All testing and data collection has been completed on the 8 subjects enrolled. Statistical analysis is currently being performed and manuscript is to be written over the next year. Manuscript is currently under second revision for publication. Everything else complete.

Adverse Effects: No adverse effects occurred in any of the subjects.

Detail Summary Sheet

Prot No: 4A88 Status: Terminated

TITLE: Are the Natriuretic and Diuretic Actions of Atrial Natriuretic Factor Dopamine Dependent?

Principal Investigator: CPT Beau J. Freund, Ph.D., MS
Associate Investigators: John R. Claybaugh, Ph.D.;
MAJ Albert H. McCullen, VC

Department/Section: Clinical Investigation/Biochemistry

Key Words: atrial natriuretic factor(ANF);

Funding: FY 89: $948 FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminate

OBJECTIVE: 1) To document a diuresis and natriuresis during blood volume expansion with isotonic saline using the adult female goat as the experimental model. 2) To determine the response of atrial natriuretic factor (ANF) and dopamine to saline infusion. 3) To determine if a dopamine antagonist (Haloperidol or Domperidone) can blunt the infusion induced diuresis or natriuresis. 4) To determine any interactive effects of other fluid regulating hormones, i.e., plasma renin activity, aldosterone, or antidiuretic hormone.

TECHNICAL APPROACH: Ten female goats will be surgically prepared with an exteriorized carotid loop. Following recovery from surgery (minimum 2 weeks) experimental procedures to include bladder catheterization and blood volume expansion via saline infusion will occur both with and without dopamine blockade with haloperidol. Renal and hormonal responses will be evaluated and statistically compared between the dopamine antagonist and control conditions.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Due to other laboratories recently completing and publishing on very similar experiments we have decided not to further pursue this protocol. Goats were utilized in other protocols of Dr. John Claybaugh.

Detail Summary Sheet

Prot No: 57H89 Status: Completed

TITLE: Effect of Negative Pressure Breathing on Fluid and Electrolyte Balance in Human Subjects

Principal Investigator: Roy A. Hebden, Ph.D.
Associate Investigators: John R. Claybaugh, Ph.D., CPT Beau Freund, MS; Glenn Hashiro; Aileen K. Sato; Wayne Ichimura

Department/Section: Clinical Investigation/Physiology Section

Key Words: electrolyte;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: The purpose of this study will be to examine the effect of negative pressure breathing on water and electrolyte homeostasis in human subjects.

TECHNICAL APPROACH: Nine healthy male subjects between the ages of 20 - 35 years of age were recruited for this study. We compared urine flow and electrolyte excretion and associated water and electrolyte regulating hormones in the same subjects during one hour of normal breathing and one hour of negative pressure breathing (NPB).

PROGRESS: No. of Subjects Enrolled - To Date: 9 Reporting Period: 1 year

Our study is different than most previously published work in this area because others have employed continuous negative pressure on the respiratory cycle. That is, both inspiration and expiration are against negative pressure. The current study was intended to mimic a more physiological situation where negative pressure is only on the inspiratory side of the cycle. We used a negative pressure of -15 cm H_2O. In general, our results go the same direction as previous studies, but the responses are not as large and sometimes fail to reach statistical significance.

Thus, our study showed that NPB caused a significant reduction in plasma renin activity, but vasopressin, aldosterone, and ANF were unaltered. There was a slight increase in urine flow which was accountable to an increase in GFR and Na excretion. We feel that the data argue against a significant role of the classic Gauer-Henry reflex accounting for the diuresis associated with NBP.

ABSTRACT (published): Hebden, R.A.; Freund, B.J.; Claybaugh, J.R.; Ichimura, W.M.; and Hashiro, G.M. Renal, hormonal, and cardiovascular responses to negative pressure breathing in man. FASEB J 4:A 413 (abstract 847), 1990.

MANUSCRIPT (submitted): Hebden, R.A.; Freund, B.J.; Claybaugh, J.R.; Ichimura, W.M.; and Hashiro, G.M. Effect of inspiratory phase negative pressure breathing on urine flow in human subjects. Eur J Physiol (submitted).

Detail Summary Sheet

Prot No: 27A89 Status: Completed

TITLE: The Prevalence of Hantavirus and Hantavirus Antibody in Rats on Oahu

Principal Investigator: MAJ Albert H. McCullen, VC
Associate Investigators: MAJ Michael J. Langford, VC

Department/Section: Clinical Investigation/Veterinary Service

Key Words: Hantavirus Antibody

Funding: FY 89: $3,309 FY 90: $7,282 Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: The objective of this proposed study is to elucidate the ecology of Hantavirus in both free running and laboratory rats on Oahu. The general approach to this problem will be to conduct a survey of laboratory and free running wild rats on Oahu to establish the presence of Hantavirus sp. and to determine its distribution. Seropositive rats will be examined to detect viral antigen in tissue and an attempt will be made to isolate the virus from antigen positive lung tissues. If isolation is successful the virus will be characterized biologically, immunologically, and antigenically.

TECHNICAL APPROACH: Blood samples will be obtained from laboratory rat and wild rat populations on the island of Oahu to screen for Hantavirus antibody. If animals have positive antibody titers to the virus, isolation and characterization will be attempted.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

All lab work has been completed on this project. Write up for publication and presentation in an appropriate form is currently in progress.

Detail Summary Sheet

Prot No: 13A90	Status: Ongoing
TITLE: Effect of Neonatal Diet on Vascular Relaxation in Normotensive and Hypertensive Rats	
Principal Investigator: Kenneth T. Nakamura, M.D. Associate Investigators: Venkataraman Balaraman, M.D.; MAJ Edward Stevens, MC; CPT Bruce Pichoff, MC	
Department/Section: Clinical Investigation	
Key Words:	
Funding: FY 89: FY 90: Gifts: AHA $25,000	Periodic Review Date: Sep 90 Decision: Continue

OBJECTIVE: To determine if dietary alterations during the early postnatal period affect vasodilatory mechanisms and the development of hypertension in normotensive and genetically hypertensive rats.

TECHNICAL APPROACH: The technique of artificial rearing by gastrostomy of preweaning SHR and WKY rats will be employed to control postnatal diet to test the hypothesis that genesis of hypertension is related in part to dietary alterations effecting mechanisms controlling vascular smooth muscle relaxation during the postnatal period. The "In vitro" isometric force technique on thoracic aorta will be used to test the specific aims that high sodium intake reduces and high calcium intake augments: 1) Vascular calcium antagonist efficacy and 2) cGMP mediated vascular mechanisms of relaxation differentially in developing WKY and SHR. Studies herein will permit full control over early diet and will provide a unique opportunity to determine unequivocally the effect of milk sodium and/or calcium content on vascular vasodilatory mechanisms involved in blood pressure control.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Studies have just begun. SHR and WKY breeding colonies have been established successfully. Initial experiments are determining the contractile response of 2 - 3 day, 6, 12, 18 and 60 day old SHR and WKY rats to norepinephrine, arginine, vasopressin and Bay K 8644, a calcium channel agonist. Dietary alterations are planned to start in early 1991.

Detail Summary Sheet

Prot No: 13A89 Status: Terminated

TITLE: Effects of Hyperoxia on Airway Smooth Muscle Function in Newborn Guinea Pigs

Principal Investigator: Kenneth T. Nakamura, M.D.
Associate Investigators: John R. Claybaugh, Ph.D.;
MAJ W. Michael Southgate, MC; Linda Kullama, Ph.D.

Department/Section: Clinical Investigation/Physiology

Key Words: hyperoxia;

Funding: FY 89: FY 90: $5,058 Periodic Review Date: Sep 90
Gifts: Decision: Terminate

OBJECTIVE: To determine if generalized or selective change of newborn guinea pigs airway smooth muscle responsiveness occurs in oxygen-induced injury. We will examine contractile and relaxation responses of isolated newborn guinea pig tracheal smooth muscle rings following randomization to room air or 95% oxygen for 2 days.

TECHNICAL APPROACH: Guinea pigs will be euthanized and trachea/bronchi will be removed. Isometric force will be recorded using standard organ tissue baths with rings bathed in Kreb's solution at T 37% with 95% OH2Y - 5% CO_2. Agonists and antagonists will be added to the muscle bath and tension recorded via a Grass FT .03 force-displacement transducer coupled to a Gould recorder. Tissue will be examined histologically employing standard H & E staining and Giemsa stains.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

This protocol has been replaced by TAMC protocol 63A89.

Detail Summary Sheet

Prot No: 38A88 Status: Ongoing

TITLE: The Ontogeny of cGMP Mediated Relaxation in Smooth Muscle (e.g. aorta, pulmonary artery, trachea etc.,) of Developing Fetal, Newborn and Adult Guinea Pigs and Rats

Principal Investigator: Kenneth T. Nakamura, M.D.; John R. Claybaugh, Ph.D.
Associate Investigators: Venkataraman Balaraman, M.D.;

Department/Section: Clinical Investigation/Physiology

Key Words: ontogeny;

Funding: FY 89: $21,164 FY 90: $11,832 Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: The objective of this study is to determine the ontogeny of cGMP mediated relaxation in smooth muscle (isolated vascular rings, tracheal rings etc.,) of developing fetal, newborn and adult guinea pigs and newborn and adult rats. We will use three different classes of pharmacological agents which stimulate cGMP by different mechanisms, viz., directly at the level of smooth muscle, receptor mediated release and endothelium dependent relaxing factor (EDRF) mediated release.

TECHNICAL APPROACH: Isolated smooth muscle structures (vascular rings, tracheal rings) are mounted in isolated organ bath and bathed in Kreb's solution aerated continuously with 95%O_2, 5%CO_2. Isometric relaxation responses are studied by addition of cumulative doses of drugs mediating relaxation after the tissue if preconstricted with a known constricting agent. The responses are recorded using a Grass .03FT force displacement transducer attached to a Gould recording device. Thus dose response curves to the various relaxing agents are generated and differences compared using standard statistical tests.

PROGRESS: ABSTRACTS: Stevens, E.L.; Balaraman, V.; Southgate, W.M.; Nakamura, K.T.: Ontogeny of sodium nitroprusside and atriopeptin III relaxation in guinea pig airway smooth muscle. Pediatric Res 27: 65A, 1990.

PRESENTATIONS: 1) Society for Pediatric Research, Anaheim, CA, May 9, 1990. 2) COMPRA Meetings, Aspen, CO, July 8, 1990.

PUBLICATIONS: Balaraman, V.; Kullama, L.K.; Easa, D.; Robillard, J.E.; Hashiro, G.M.; Nakamura, K.T.: Developmental changes in sodium nitroprusside and atrial natriuretic factor mediated relaxation in the guinea pig aorta. Pediatric Res: 27: 392-395, 1990.

Detail Summary Sheet

Prot No: 58A89 Status: Ongoing

TITLE: The Ontogeny of "Cyclic Guanosine Monophosphate (cGMP) Dependent" and "cGMP Independent" Relaxation Mediated by Sodium Nitroprusside (SNP) and Atrial Natriuretic Factor (ANF) in the Thoracic Aorta of Guinea Pigs

Principal Investigator: Kenneth T. Nakamura, MD
Associate Investigators: Venkataraman Balaraman, MD; Linda K. Kullama, Ph.D.; Aileen K. Sato; Naomi Fujiwara; John R. Claybaugh, Ph.D; MAJ Edward Stevens, MC; CPT Bruce Pichoff, MC

Department/Section: Department of Clinical Investigation

Key Words: Cyclic Guanosine Monophosphate (cGMP)

Funding: FY 89: FY 90: $6,448 Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: This proposed study is designed to define the ontogeny of "cGMP dependent" and "cGMP independent" relaxation in the thoracic aorta of guinea pigs mediated by SNP and ANF. Aortae from fetal, newborn and adult guinea pigs will be studied.

TECHNICAL APPROACH: Relaxation responses will be measured employing the isolated vessel technique measuring isometric force. cGMP will be extracted and assayed by RIA employing a commercially available kit (New England Nuclear). Protein content will be assayed according to the technique described by Lowrey.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

ABSTRACTS: Balaraman, V.; Kullama, L.K.; Fujiwara, N.; Sato, A.K.; Nakamura, K. T.: Mechanisms of CGMP dependent relaxation to sodium nitroprusside and atriopeptin III in aorta of fetal and adult guinea pigs. Pediatric Res 27: 56A, 1990.

PRESENTATIONS: Society for Pediatric Research, Anaheim, CA, May 8, 1990.

Detail Summary Sheet

Prot No: 63A89 Status: Ongoing

TITLE: Ontogeny of Airway Smooth Muscle Function

Principal Investigator: Kenneth T. Nakamura, M.D.
Associate Investigators:

Department/Section: Clinical Investigation

Key Words:

Funding: FY 89: FY 90: Periodic Review Date:
Gifts: $346,226 (7/1/90 - 6/30/95) Decision: Continue
NIH R29 HL45220

OBJECTIVE: To define if exposure to high oxygen concentrations during the newborn period alters the normal developmental progression of airway smooth muscle function. We will examine contractile and relaxation responses of isolated newborn guinea pig airway smooth muscle rings following randomization to room air or 95% oxygen for 2 days.

TECHNICAL APPROACH: The overall hypothesis that exposure to high oxygen concentrations during the newborn period alters the normal developmental progression of airway smooth muscle function will be examined in vitro. Six groups of Hartley albino guinea pigs will be studied. Each guinea pig will contribute four airway ring segments: 2 adjacent segments of extra-thoracic trachea, right and left mainstem bronchus. Regional differences among the large airways vary with regards to histology, functional response to agonists and epithelium removal. Thus, we expect to observe differences between trachea and bronchi, with each having a paired control for experiments conducted during this study.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Abstracts:

Southgate WM, Pichoff BE, Balaraman, V, Kullama LK, Uemura HS, Nakamura KT: Age Variable Effects of Epithelium Removal on Guinea Pig Airway Smooth Muscle Response to Acetylcholine and Histamine. Pediatr Res 27:318A, 1990.

Uyehara CFT, Pichoff BE, Nakamura KT: Oxygen Exposure Enhances Airway Reactivity in Newborn Guinea Pigs. Clin Res (In Press).

Stevens EL, Balaraman V, Southgate WM, Nakamura KT: Ontogeny of sodium, Nitroprusside and Atriopeptin III Relaxation in Guinea Pig Airway Smooth Muscle. Pediatr Res 27:65A, 1990.

Current Projects in preparation for submission to the Annual Meeting of the Society for Pediatric Research:
1 - Effect of Bay K 8644 on airway smooth muscle in newborn and adult guinea pigs
2 - Lasix relaxes airway smooth muscle

Detail Summary Sheet

Prot No: 2H90 Status: Completed

TITLE: Simultaneous Orthognathic Surgery and Cervicofacial Liposuction Questionnaire

Principal Investigator: LTC Durwood E. Bach, DC
Associate Investigators: COL Ricney F. Newhouse, DC

Department/Section: Dentistry/Oral Maxillofacial Surgery Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: To determine the frequency of combined orthognathic surgery and liposuction among oral and maxillofacial surgeons. To determine prevalent techniques, complications and general results of these combined procedures.

TECHNICAL APPROACH: A 29-question survey will be sent to the directors of all Oral Maxillofacial Surgery training programs recognized as meeting criteria for accreditation by the American Association of Oral Maxillofacial Surgeons and Accreditation Committee of the American Dental Association. Following return of the surveys, responses will be analyzed and tabulated. Accumulated data will be presented at a national meeting and presented in a future publication.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Results were presented at a national meeting. A manuscript was also submitted and accepted for publication.

Detail Summary Sheet

Prot No: 12A89 Status: Ongoing

TITLE: Evaluation of a Composite Graft (Porous Particulate Hydroxyapatite-Particulate Marrow Cancellous Bone) for Onlay Augmentation of the Atrophied Alveolar Ridge with Simultaneous Placement of Endosseous Implants in Goats

Principal Investigator: LTC Durwood E. Bach, DC
Associate Investigators: COL Ricney F. Newhouse, DC; MAJ Gregory Boice, DC; MAJ Steven Perkins, DC; COL Jeffrey O. Hollinger, DC

Department/Section: Dentistry/Oral Surgery

Key Words: endosseous implants;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Pending HMJFAMM Decision: Continue

OBJECTIVE: To evaluate a composite graft system for augmentation of the atrophied alveolar ridge with simultaneous placement of 2 endosseous implant systems. Clinical evaluation to assess the degree of stability of the implant. Clinical and radiographic assessment to determine the degree of bone graft maintenance or resorption postoperatively. Histologic and histomorphometric analysis to quantitate osseointegration of the dental implants within the matrix of the graft.

TECHNICAL APPROACH: Each animal will have an augmentation and simultaneous implant placement on the right and left side of the maxilla and the mandible. There will be 4 surgical/experimental sites per animal. One side of the mandible/maxilla will be augmented with an autogenous particulate marrow graft and the opposite side will be augmented with a composite graft of 50% hydroxyapatite and 50% autogenous particulate marrow. The sites will be randomized.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Study initiation pending funding through the Henry M. Jackson Foundation for the Advancement of Military Medicine (HMJFAMM).

Detail Summary Sheet

Prot No: 48A89 **Status:** Ongoing

TITLE: Microsurgery Training for Oral Maxillofacial Surgery Residents Using Rat Nerves and Vessels

Principal Investigator: LTC Durwood E. Bach, DC
Associate Investigators: COL Ricney Newhouse, DC; MAJ Gregory Boice, DC; MAJ Steven Perkins, DC; MAJ Michael Werner, DC; LTC Charles Ringhold, DC

Department/Section: Dentistry/Oral Maxillofacial Surgery Service

Key Words: oral maxillofacial;

Funding: FY 89: $5,261 FY90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To train residents in the techniques of epineural and fascicular nerve repair for nerves approximately 1mm in diameter. To train residents in the repair of arteries and veins approximately 1mm in diameter.

TECHNICAL APPROACH: Laboratory course utilizing the rat model to demonstrate performance of several surgical procedures/exercises.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period: Aug 89

A laboratory course was completed for 1990. Protocol will remain active as a training study.

Detail Summary Sheet

Prot No: 9H88 Status: Terminated

TITLE: A Comparison of Complete Maxillary Denture Retention Before and After Magnetic Retention is Obtained Utilizing Osseointegrated Implants

Principal Investigator: MAJ Gregory W. Boice, DC
Associate Investigators:

Department/Section: Dentistry

Key Words: osseointegrated implants;

Funding: FY 89: FY 90: Periodic Review Date: Sep-90
Gifts: None Decision: Terminated

OBJECTIVE: To measure the in vivo retention that is added to complete maxillary dentures by using rare earth magnets in conjunction with osseointegrated implants.

TECHNICAL APPROACH: Patients were selected on the basis of having an edentulous maxillary ridge and a suitable maxillary denture. A stainless bar was fixed to the palatal portion of the denture and reinserted into the patients' mouth. Using a Chattilion push-pull gauge, the patients' denture was pulled down and the force needed to break the seal was recorded. After those measurements were taken, 2 Interpore IMZ Titanium Endosseous implants were placed, 1 each at the maxillary canine area. The implants were allowed four months to osseointegrate then were uncovered and keepers were attached to the implants. Then 2 Jackson regular rare-earth magnets were placed in the patients' dentures in such away to achieve contact with the keepers when the dentures were fully seated. Pull out measurements were done after magnetic augmentation in the same way as before.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

One year follow-up radiographs and recall appointments are being done on all patients at this time. No new patients were enrolled during the last year. The principal investigator has PCS'd. Submittal for publication is in process.

Detail Summary Sheet

Prot No: 62H89 Status: Ongoing

TITLE: Patient Controlled Analgesia in Orthognathic Surgery

Principal Investigator: MAJ Steven J. Perkins, DDS
Associate Investigators:

Department/Section: Dentistry/Oral Maxillofacial Surgery Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To evaluate efficacy and safety of patient-controlled analgesia (PCA) modality of pain control in an orthognathic surgical patient population.

TECHNICAL APPROACH: Patients will be randomly assigned to two groups. Group I will receive the current post-operative analgesic regimen; 3 - 5 mg morphine IV q3-4h prn pain in the Surgical Intensive Care Unit. Group II patients will receive an explanation of the nature of the study and instructed in the use of the "Abbot Life Care PCA Infuser"; a bolus dose of 2 - 5 mg of morphine via the infuser will be given if needed.

For comparison of the two groups, data will consist of a constant evaluation of sedation, pain, respiratory rates, side effects and the amount of narcotic given every two hours while in the SICU and every four hours while on the ward. Pain will be ranked by the patient's oral response when questioned.

PROGRESS: No. of Subjects Enrolled - To Date: 13 Reporting Period: 13

The PCA protocol study is going well without any complications to date. All patients to date have had no complaints with the study. The proposed dosage regimen in the protocol to be adequate. No major adjustments to the protocol have been done. There have been no technical problems with the PCA infusion pumps.

Thirteen patients are enrolled in the program and data completed. Two more patients will be enrolled this month, then we will begin with the control patients. Expected date of completion is March, 1991. Results to date have been very favorable to the use of PCA for pain control with a high level of acceptance among patients.

Detail Summary Sheet

Prot No: 64H88 Status: Ongoing

TITLE: A Comparison of Amitriptyline vs. Trazodone vs. Placebo as Adjuvants to Opiate Analgesics in the Management of Pain in Cancer Patients

Principal Investigator: COL Jeffrey L. Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words: amitriptyline; trazodone;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Amitriptyline,Trazodone & Placebo Tablets Decision: Continue

OBJECTIVE: a) Compare the relative effectiveness of amitriptyline and trazodone as adjuvants to opiate analgesics for the management of pain of malignant diseases. b) Quantify the "opiate sparing" effect of these two agents when used in conjunction with morphine sulfate. c) Evaluate the cost-efficiency/effectiveness of trazodone and amitriptyline, as adjuvants to opiate analgesics, in the treatment of pain associated with malignant disease.

TECHNICAL APPROACH: Patients agreeing to participate in the study will first be titrated to a dose of morphine sulfate that controls their pain satisfactorily. They will then be randomized to receive an additional drug (either 1. amitriptyline, 2. trazodone or 3. placebo). This will be double blind. When this additional drug is started, their morphine dose will be decreased by 25% and the patients will be monitored closely for their pain level. The patients will have constant access to additional morphine if and when they need it for breakthrough pain. The physician following the patient will be expected to adjust the regularly scheduled morphine based on any regularly occurring breakthrough pain. Patients will be followed for 60 days minimum.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Multi-institutional study to continue until study objective met. Status is ongoing.

Detail Summary Sheet

Prot No: 19H84 Status: Ongoing

TITLE: Treatment of Graves' Ophthalmopathy with Cyclosporin

Principal Investigator: COL Michael Bornemann, MC
Associate Investigators:

Department/Section: Medicine/Endocrine-Metabolic

Key Words: Graves' ophthalmopathy;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To assess the efficacy of Cyclosporin treatment on the ophthalmopathy of Graves' disease.

TECHNICAL APPROACH: This is a random crossover study comparing Cyclosporin therapy of Graves' ophthalmopathy versus the standard of current therapy, high-dose oral Prednisone. Because of potential toxicity, this is not a double-blind study. The drugs will be administered for three weeks each, and then the patient will be crossed over with clinical response measured by an ophthalmopathy index. There will be a pretherapy clinical assessment and the usual laboratory testing pre-, post-, and during therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This Walter Reed collaborative protocol remains open anticipating any patients that might meet the study population criteria. No (new) subjects enrolled. Recommend on-going status. This is part of an Army-wide project with centralized support WRAMC.

Detail Summary Sheet

Prot No: 33H86 Status: Ongoing

TITLE: The Natural History of HTLV-III Infection and Disease in a United States Military Population

Principal Investigator: COL Joel D. Brown, MC
Associate Investigators: Dr. Arthur Johnson, M.D.

Department/Section: Medicine/Infectious Disease Service

Key Words: HTLV-III; AIDS; infection;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To assess the impact of HTLV-III infection on military readiness by defining the natural history of infection in the general military population and to form a study cohort upon which subsequent studies can be built.

TECHNICAL APPROACH: Personnel with confirmed HTLV-III infection who agree to participate will receive standard evaluation, counseling, and referral of contacts. Information will be centralized in a common data base. Serum and CSF samples will be stored at WRAIR for future testing. Follow-up studies will be performed every six months.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study enrolls volunteer HIV infected patients for epidemiologic and periodic clinical evaluation to determine the course of their disease over time. It is part of a multicenter protocol, and the study will continue for at least 1 more year. No investigational agents are involved therefore there were no adverse results.

Results: A total of 171 patients entered the study to date. Forty-six patients were enrolled in 1990. No publications were submitted by TAMC since it is a multi-centered study.

Detail Summary Sheet

Prot No: 8H89 Status: Completed

TITLE: Evaluation of Anamnestic Response of Lymphocytes from Recipients of the Heptavax Vaccine who are HBsAb Negative

Principal Investigator: CPT Albert G. Fedalei, MC
Associate Investigators:

Department/Section: Medicine

Key Words: heptavax vaccine;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: To determine if the lymphocytes from subjects who have previously received the Heptavax but are now HBsAb negative, are able to mount an anamnestic response to antigen challenge.

TECHNICAL APPROACH: Physicians and ancillary staff at Tripler Army Medical Center who received the Heptavax vaccine between 1981 and 1986 were identified by questionnaire. To date, 43 subjects met the initial criteria and were tested for antibody to the surface antigen of hepatitis B (HBsAb). Initial screen utilized an ELISA assay whose positive/negative cutoff corresponded to a cutoff level of 10 S.R.U. by RIA. Three subjects (approximately 7%) were found to be antibody negative. These were matched with HBsAb positive controls for age, sex, site of injection and time vaccine was administered. Peripheral blood mononuclear cells were isolated by differential Ficoll-Hypaque gradient centrifugation. The cells were washed and then suspended in culture medium in microtiter well plates. Stimulation was provided by use of PHA, Hepatax or Recombivax. One microgram of hepatitis B antigen was found to be optimal in preliminary studies. After stimulation, cells were labeled with tritiated thymidine to measure increased cell activity. The lymphocytes from all subjects showed significant stimulation in response to phytohemagglutinin (PHA).

PROGRESS: No. of Subjects Enrolled - To Date: 91 Reporting Period: 91
The lymphocytes from all subjects showed significant stimulation in response to phytohemagglutinin (PHA). HBsAb negative subjects all had a blast index of less than one. Two of the three antibody positive controls and a separate internal positive control had blast indexes between 1.43 and 3. The antibody positive individual with a blast index less than 1 was found to also have very low titer antibody on serial dilution. These data suggest that the immediate anamnestic humoral immune response to the HB vaccine is virtually absent in antibody negative vaccine recipients and very poor even in those who have effective titers of circulating antibody. THis supports the need for hepatitis B vaccine booster injections to maintain high levels of circulating antibody.

Detail Summary Sheet

Prot No: 17H88 Status: Ongoing

TITLE: Impact of Clinical Laboratory Methodology on the Accurate Measurement of Serum Chloride and Calculated Bicarbonate from Arterial Blood Gases and the Clinical Approach to the Diagnosis of Acid-Base Disorders

Principal Investigator: MAJ L. Harrison Hassell, MC
Associate Investigators:

Department/Section: Medicine

Key Words: serum chloride;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: a. To determine the effect of the clotted RBC mass on the accurate measurement of serum chloride and calculated bicarbonate from arterial blood gases b. To determine the effect of air exposure on the accurate measurement of serum chloride and calculated bicarbonate from arterial blood gases. c. To test the clinical maxim, "arterial blood gas values should be validated before being used in clinical decision making."

TECHNICAL APPROACH: Arterial blood is sampled and divided into a series of blood tubes designed to assess effects of various post-phlebotomy effects on the laboratory determination of the serum bicarbonate. This data is combined with arterial blood gas measurements to determine whether post-phlebotomy effects will alter the diagnosis of acid-base disorders.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period:

This study is laboratory intensive and requires extensive computer programming to account for all variable effects. However, the question is still valid. The protocol will be initiated in November, 1990.

Detail Summary Sheet

Prot No: 8L87 Status: Ongoing

TITLE: Noncompliant Behavior Among Hemodialysis Patients: Relationship to Disturbances of the Renin-Angiotensin-Aldosterone, Antidiuretic Hormone, and Atrial Natriuretic Hormone Axes

Principal Investigator: MAJ L. Harrison Hassell, MC
Associate Investigators: John R. Claybaugh, Ph.D.; Arnold Siemsen, MD; Jon Streltzer, MD

Department/Section: Medicine/Nephrology

Key Words: hemodialysis patients;

Funding: FY 89: $323 FY 90: Periodic Review Date: Sep 90
Gifts: none Decision: Continue

OBJECTIVE: Designed to compare levels of plasma renin activity (PRA), aldosterone (PA), antidiuretic hormone (ADH), and human atrial natriuretic peptide (hANP) in compliant and noncompliant hemodialysis patients to those in both humans and experimental animals associated with stimulation of thirst and salt appetite. Abnormalities of these hormonal axes may provide inferential evidence of disturbances of thirst and salt appetite which may underlie noncompliant behavior.

TECHNICAL APPROACH: Hemodialysis patients have blood drawn before and after two consecutive hemodialysis treatments. Urine is collected in the interim to calculate residual renal function. Patients have been categorized according to pre-defined criteria of compliance as assessed by interhemodialytic weight gain. The study will evaluate relationships of hormonal abnormalities to compliant and noncompliant behavior.

PROGRESS: No. of Subjects Enrolled - To Date: 9 Reporting Period: 1

No adverse effects have occurred. Results of the study were presented at the 1989 FASEB meeting (LHH) and the 18th European Conference on Psychosomatic Research in Helsinki, Finland. Manuscript preparation in progress.

Detail Summary Sheet

Prot No: 43H89*	Status: Ongoing
TITLE: Clinical Utility of Post-Thoracentesis Chest Roentgenography	
Principal Investigator: CPT Mark G. Kortepeter, MC Associate Investigators: CPT William D.Holland, MC; MAJ John D. Olsen, MC CPT Oleh Hnatiuk, MC	
Department/Section: Medicine	
Key Words: post-thoracentesis; roentgenography	
Funding: FY 89: NA FY 90: NA Gifts: None	Periodic Review Date: Sep 90 Decision: Continue

OBJECTIVE: The purpose of this study is to prospectively assess whether the routine use of post-thoracentesis chest roentgenography in asymptomatic patients without clinically apparent complications is warranted. This prospective study hopes to provide unbiased, well documented evidence needed to calculate an accurate negative predictive value for the parameters identified in our retrospective review.

TECHNICAL APPROACH: No alteration form basic standards of medical practice. Follow up of patient's thoracentesis will involve reviewing thoracentesis form and reviewing CYR.

PROGRESS: No. of Subjects Enrolled - To Date: 23 Reporting Period: 9 mo.

Due to delay in receiving standardized thoracentesis forms (received 14 Sep) project initiated 15-18 Sep 89. No subjects at present.

*Exempt from committee protocol (retrospective study).

Detail Summary Sheet

Prot No: 10H89 Status: Ongoing

TITLE: Double Blind Trial of Sucralfate in the Treatment of Minor Aphthous Stomatitis

Principal Investigator: CPT James K. Howden, MC
Associate Investigators:

Department/Section: Medicine

Key Words: sucralfate; aphthous stomatitis;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: Recurrent aphthous stomatitis, commonly known as canker sores, is estimated to affect 20 percent of the general population. (1) Effective therapy of the common idiopathic aphthous ulcerative type is not available. Because of promising results in the therapy of chemotherapy associated oral mucositis, a therapeutic trial with sucralfate is proposed.

TECHNICAL APPROACH:

After being assessed through questionnaire, short physical exam and complete blood count, patients are randomly assigned, in blinded fashion, to either the treatment or placebo group. The patient's consent is obtained and he is given a prescription. The patient is instructed to begin therapy on the initiation of symptoms and to call the Internal Medicine Clinic to arrange follow up within one day. The patient is thereafter seen every two days for a total of ten days to assess for subjective and objective improvement.

PROGRESS: No. of Subjects Enrolled - To Date: 30 Reporting Period: 15

Presently the collection of data is on going. There have been no adverse effects or patients dropped/withdrawn from the study to date.

Detail Summary Sheet

Prot No: 27H83 Status: Terminated

TITLE: A Treatment Protocol for the Use of Trimetrexate with Leucovorin Rescue for AIDS Patients with Pneumocystis Carinii Pneumonia and Serious Intolerance to Approved Therapies

Principal Investigator: Dr. Arthur C. Johnson, M.D.
Associate Investigators: COL Joel D. Brown, MC

Department/Section: Medicine/Infectious Disease

Key Words: leucovorin; Pneumocystis Carinii pneumonia (PCP);

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: To make available this treatment approach to our patients pending FDA approval. To add to existing information on the safety and efficacy of trimetrexate with leucovorin rescue in AIDS patients with Pneumocystis Carinii pneumonia (PCP) who have no therapeutic alternatives because they have demonstrated serious (severe or life threatening) intolerance to both conventional therapies for PCP.

TECHNICAL APPROACH: Treatment protocol (national).

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Accrual of subjects has been significantly less than initially anticipated. No publications were submitted by TAMC since this is a multi-center study.

Detail Summary Sheet

Prot No: 31H90 Status: Ongoing

TITLE: Evaluation of Autopsy Results of AIDS Autopsies in Hawaii; 1981 to Date

Principal Investigator: Dr. Arthur C. Johnson, MD
Associate Investigators: Lee Ann Mullen

Department/Section: Medicine/Infectious Disease

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: The purpose of this study will be to see how data from a Hawaii Autopsy series compares to national data. It is possible that because of Hawaii's unique ethnic makeup and geographic location that this might contribute to the understanding of the pathophysiology and treatment of AIDS, if not presently, then at some later date.

TECHNICAL APPROACH: Autopsy reports and medical records of all patients with AIDS autopsied on Oahu will be reviewed. Data will then be collated and used to establish a computerized database which will be analyzed for the variables listed in the objectives.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: 30H90 Status: Ongoing

TITLE: An Open Study of Foscarnet Treatment of CMV retinitis in AIDS Patients Who Demonstrated DHPG (Ganciclovir) Treatment Failure or Toxicity

Principal Investigator: Dr. Arthur C. Johnson, MD
Associate Investigators: COL Joel D. Brown, MC

Department/Section: Medicine/Infectious Disease

Key Words: Foscarnet, cytomegalovirus (CMV) retinitis

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To make Foscarnet available to patients with CMV retinitis who have failed Ganciclovir and to evaluate the safety and toxicity of Foscarnet in these patients.

TECHNICAL APPROACH: Treatment protocol.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: 32H90 Status: Ongoing

TITLE: Stool Survey of Persons with HIV Disease

Principal Investigator: Dr. Arthur C. Johnson, MD
Associate Investigators: Al Katz, MD; David Morens, MD; COL Joel D. Brown, MC

Department/Section: Medicine/Infectious Disease

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To evaluate possible changes which occur over time, in the amount and kinds of bacteria and parasites living in the lower gastrointestinal tract of patients who are infected with HIV.

TECHNICAL APPROACH: Patients agreeing to participate in this study will provide stool specimens for examination upon regular checkups and whenever ill with a gastrointestinal illness.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: 11H88 Status: Ongoing

TITLE: Efficacy of Steroids in the Acute Treatment of Asthma: Are Duration of Symptoms Important?

Principal Investigator: MAJ Marcia L. Muggelberg, MC
Associate Investigators: MAJ T. R. Vaughan, MC

Department/Section: Medicine/Allergy-Immunology Service

Key Words: efficacy of steroids; asthma;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine whether the efficacy of steroids for the treatment of asthma in the acute setting is related to the duration of the patients' symptoms for that episode of asthma.

TECHNICAL APPROACH: Prospective data collection; standard patient care.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period:

This study was active only a couple of months then put on hiatus because of our move to the new area. We are coordinating with the Emergency Room to actively enroll patients again.

Detail Summary Sheet

Prot No: 12H88 Status: Ongoing

TITLE: Multicenter Clinical Evaluation of Penicillin Skin Testing Materials

Principal Investigator: MAJ Marcia L. Muggelberg, MC
Associate Investigators:

Department/Section: Medicine/Allergy-Immunology Service

Key Words: penicillin allergy;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: 1) To determine whether there is a difference is the incidence of skin test positivity to the different skin testing reagents prepared by different methods in patients with a history of penicillin allergy as well as in subjects with no previous history of an adverse reaction to a penicillin-like drug. 2) To study the comparative potency, as determined by cutaneous endpoint titration skin testing, of reagents prepared by difference methods in skin test positive patients. 3) To compare skin test reactivity to freshly reconstituted reagents with that produced by aged reagents.

TECHNICAL APPROACH: Test-arm trials.

PROGRESS: No. of Subjects Enrolled - To Date: 17 Reporting Period: 17

Ongoing number of subjects enrolled is 17. One positive reaction to Penicillin; one positive reaction to minor determinant.

Detail Summary Sheet

Prot No: 32H89 Status: Ongoing

TITLE: The Effect of Cancer Chemotherapy on the Reactivation of Chronic Hepatitis B Infection

Principal Investigator: CPT Rickey C. Myhand, MC
Associate Investigators: COL Jeffrey Berenberg, MC;
COL Charles C. Jones, MC;
COL Joseph Woods, MC; LTC Bruce A. Cook, MC

Department/Section: Medicine

Key Words: chronic hepatitis B;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: Cases of reactivation of chronic hepatitis B infection with resultant acute hepatitis and death have been described in the literature. The changing status of hepatitis B infection in patients who receive cancer chemotherapy has not been evaluated in a prospective study. Specific questions to be addressed by this study are: 1) Does hepatitis B reactivation and subsequent liver damage occur frequently in chronic carriers who receive cancer chemotherapy for malignancy? 2) Should candidates for cancer chemotherapy be routinely screened for chronic hepatitis B infection? 3) Is there a morphologic/histopathologic distinction between chemotherapy induced hepatotoxicity and viral induced liver disease?

TECHNICAL APPROACH: Screen patients receiving or about to receive chemotherapy (screen for positive HBsAg). If positive, obtain consent to enter study. When consent is obtained, obtain baseline studies of HBsAg, Delta Ag and Ab, HBcAB (IgM, IgG), HBeAg, HBeAb, HB serum DNA probe, HAV Ab, SGOT, SGPT, GGT, T bili, Alkaline Phosphatases, T-Helper/Suppressor ratio, cytotoxic T-cell. Liver biopsy (excluding pediatric patients) upon entrance of study and at the completion of chemotherapy regimen. Follow baseline studies monthly. Total number of patients required for study: 15-20 Duration of study: 2 years.

PROGRESS: No. of Subjects Enrolled - To Date: 3 Reporting Period: 3

Two liver biopsies have been done, both without complications. No subjects have been dropped or withdrawn.

Detail Summary Sheet

Prot No: 55H88 Status: Ongoing

TITLE: A Direct Comparison Between the Cholesterol Lowering Effects of Psyllium Mucilloid and Bile Sequestering Agents

Principal Investigator: CPT Timothy Pfanner, MC
Associate Investigators: CPT Steven E. Hill, MC; CPT Gary Gazenski, MC; MAJ Suzanne Chang, RD

Department/Section: Medicine

Key Words: psyllium mucilloid;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To show that psyllium mucilloid is more efficacious than the bile sequestrant cholestyramine in reducing total serum cholesterol and low density lipoprotein.

TECHNICAL APPROACH: Two arm outcome study of approved medications.

PROGRESS: No. of Subjects Enrolled - To Date: 77 Reporting Period: 77

Dr. Pfannner's two month absence and a downgrading of support by dietary has necessitated changing the study site to the cardiology clinic. The basic clinic and dietary consulting are being provided by Joan Pitacciato, R.N. who is also to be appointed as a co-investigator in the project. This will allow the clinic and project to continue despite Dr. Pfanner's absence. We are currently gearing up again to admit more patients to the study, however at least 12 more months will be needed.

Detail Summary Sheet

Prot No: 8H90 Status: Ongoing

TITLE: Seroepidemiologic Survey and Risk Factor Analysis for Hantavirus Infection in Infantry Soldiers Stationed in Hawaii

Principal Investigator: MAJ Leo D. Tucker, II, MC
Associate Investigators:

Department/Section: Medicine

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine the prevalence of infection by Hantavirus in infantry soldiers stationed in Hawaii. Additionally, to evaluate the risk factors for Hantavirus infections in this population.

TECHNICAL APPROACH: Human sera was collected from volunteers. Serologic evaluations of human sera for antibody to Hantavirus was conducted using enzyme linked immunosorbant assay (ELISA) technique.

PROGRESS: No. of Subjects Enrolled - To Date: 500 Reporting Period:

To date greater than 500 individual soldiers were tested for antibody to Hantavirus. There are no positive results from the sera of those tested. This indicates that the individuals tested were not infected by the Hantavirus. The donated antigen utilized in this test has been completely utilized in the testing performed to date. The investigators are currently evaluating the project to determine if it should be continued. If it is continued, additional antigen will be needed and will need to be purchased.

Detail Summary Sheet

Prot No: 22H90 Status: Ongoing

TITLE: Effects of Aspirin vs. Coumadin on the Prevention of Calf-Vein DVT Progression to Proximal DVT

Principal Investigator: CPT Howard Zimring, MC
Associate Investigators: William J. Thomas, MC

Department/Section: Department of Medicine

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: 1) Can aspirin provide protection equivalent to Coumadin in: preventing the progression of calf vein DVT to Proximal DVT. 2) Is Aspirin a safer treatment option for calf vin DVT compared to Coumadin and placebo.

TECHNICAL APPROACH: Patients will be randomized in blocks into the treatment groups after a diagnosis of DVT confined to the calf has been made by venogram. Patients will then be assigned in blocks of three to one of three groups and further classified with regard to the type of calf-vein DVT initially found on the venogram. Patients will undergo clinical exam and duplex ultrasound to assess compressibility of popliteal vein/femoral vein system upon diagnosis and then again at specified intervals. Compliance with drug therapies will be evaluated by interviews with the patients, pill counts, prothrombin-time monitoring and testing of urinary salicylate levels.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start. No progress to report.

Detail Summary Sheet

Prot No: 2H86 Status: Terminated

TITLE: Systolic Hypertension in the Elderly Program

Principal Investigator: CPT Howard J. Zimring, MC
Associate Investigators: Dr. Helen Petrovitch, M.D.
(Principal Investigator in Hawaii for the national SHEP study)

Department/Section: Medicine

Key Words: hypertension;

Funding: FY 89: NIH* FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: To assess whether long-term administration of antihypertensive therapy to elderly subjects with isolated systolic hypertension reduces the combined incidence of fatal and nonfatal stroke.

TECHNICAL APPROACH: The study will be a double-blind, placebo-controlled, randomized clinical trial. Half of the participants will be given active intervention using a step-up treatment program. The other half will be randomly assigned to placebo.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
Reporting Period: N/A

Study terminated. No one at Tripler has elected to or is interested in participating in this study.

*(Division of Heart, Lung and Blood)

Detail Summary Sheet

Prot No: 16H90 Status: Completed

TITLE: Incidence of Oxygen Desaturation in Healthy Adults During Transport from the Operating Room to the Post Anesthesia Care Unit

Principal Investigator: CPT Nathaniel M. Apatov
Associate Investigators:

Department/Section: Nursing

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: The purpose of the study is to determine if healthy adult patients desaturated as measured by pulse oximetry during transportation from the operating room to the post anesthesia care unit.

TECHNICAL APPROACH: Data collection began in the operating room at the conclusion of the surgical procedure. After minimal transport criteria were met, 5 pulse oximetry readings were taken during the transport process, the initial reading just prior to moving from the O.R. table to the transport stretcher. Four other readings were noted during the transport process to include the lowest saturation reading during transport as well as a final reading upon arrival to the post anesthesia care unit. If oxygen saturation dropped during transport, we intervened using Dorothea Orem's Self Care Deficit Theory as a framework for structuring interventions used to maintain oxygen saturation. If oxygen saturation decreased below 90%, supplemental oxygen was applied.

PROGRESS: No. of Subjects Enrolled - To Date: 105 Reporting Period:

Results of our study showed that more than half of our subjects (n=55) desaturated between 3 and 13 percentage points during transport, with the average desaturation being 2.97%. Desaturation among patients undergoing upper abdominal procedures (n=9) was statistically significant (p=0.05) supporting prior research.

The researchers concluded that there is a significant incidence of desaturation in this population.

Detail Summary Sheet

Prot No: 40H89 Status: Ongoing

TITLE: A Blinded HIV Seroprevalence Survey Utilizing Cord Blood Specimens Routinely Collected for Neonatal RH Antibody Titer and Hematocrit Testing

Principal Investigator: LTC Margaret M. Baird, RN, MS
Associate Investigators: Dr. Patricia Nishimoto, Ph.D., RN

Department/Section: Nursing

Key Words: HIV seroprevalence;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To identify HIV Seroprevalence in childbearing women in Honolulu, as one of 30 metropolitan areas in an ongoing CDC study. The purpose is to define risk areas for targeting education for prevention and future resources for care and treatment.

TECHNICAL APPROACH: An additional take of cord blood will be obtained at the time of delivery to test for HIV Seroprevalence.

PROGRESS: No. of Subjects Enrolled - To Date: Approximately 3,600
Reporting Period: n/a

The study was not started until October 1989 due to shipping delays for such materials as cord blood collection tubes, racks and labels and demographic sheets. Over 25 nurses from TAMC and the army reserve unit have participated in the study so far as data collectors. The support from the TAMC laboratory has been outstanding.

Detail Summary Sheet

Prot No: 53H89 Status: Completed

TITLE: The Effect of Therapeutic Massage on Patient's Back Pain after Cardiac Catheterization

Principal Investigator: Lolita A. Ching, RN
Associate Investigators:

Department/Section: Nursing/Medical Intensive Care Unit

Key Words: therapeutic massage

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To determine if therapeutic massage has an effect on the patient's back pain after cardiac catheterization. To determine if patients who receive therapeutic massage will decrease the rate of back pain as measured by the visual analogue scale than the patients who do not receive therapeutic massage.

TECHNICAL APPROACH: The study utilized a non-equivalent pretest posttest contro quasiexperimental design. A convenience sample of 30 subjects with 15 subjects in each group will be given a visual analogue scale to rate the pain intensity before and after the intervention.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Study completed.
Patients who received therapeutic massage had a significant reduction of back pain clinically as compared to patients who repositioned on the right side.

Detail Summary Sheet

Prot No: 18H90 Status: Ongoing

TITLE: Parental Facilitated Guided Imagery and Relaxation For Reducing Chemotherapy Associated Nausea and Vomiting in Children With Cancer

Principal Investigator: Florence Kerfoot, RN, MS
Associate Investigators: Deborah LaFond, RN

Department/Section: Nursing/Pediatric Oncology

Key Words: Anxiety; nausea; vomiting; lifestyle disruptions; guided imagery

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: Investigate the effectiveness of parental facilitated guided imagery (muscle relaxation program) in reducing chemotherapy associated nausea and vomiting in pediatric oncology patients -- ages 3 to 10.

TECHNICAL APPROACH: Parents and child view video tape (no fears no tears), complete questionnaire, intervention (distraction with blowing and books--initially done by investigator than by parent). Parent and child then do a self report questionnaire.

PROGRESS: No. of Subjects Enrolled - To Date: 5
Reporting Period: June - September

Detail Summary Sheet

Prot No: 37H90 Status: Ongoing

TITLE: Efficacy of a Mentorship Program for Clinical Anesthesia Nursing Education

Principal Investigator: MAJ Alfred E. Lupien, AN
Associate Investigators: MAJ Harold S. Booker, AN

Department/Section: Nursing/Anesthesiology Nursing Section

Key Words: mentor, protege

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine the efficacy of a mentorship program in clinical anesthesia nursing education. Statistical hypotheses to be tested are:

a. There is no difference between protege (student) performance and AHS performance standards
b. There is no difference between overall protege (student) stress level and the stress level of the previous class of students

TECHNICAL APPROACH: Study participants potentially will consist of all 5 students entering Phase II in July 1990. Due to the limited class size, the entire class will be used as an experimental group. Matching of protege (student) and mentor will be done randomly.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: 32H88 Status: Completed

TITLE: Vasoconstriction and Anesthesia for Intranasal Surgery: Is Cocaine Really Necessary?

Principal Investigator: CPT Terry C. Wicks, ANC
Associate Investigators: CPT Timothy A. Newcomer, AN
MAJ Marc A. Paradis, MC

Department/Section: Nursing/Anesthesiology Nursing Section

Key Words: intranasal surgery; vasoconstriction;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To examine whether or not 4% lidocaine with 0.002% oxymetazoline can provide anesthesia and vasoconstriction comparable to 4% cocaine when applied topically. Is epinephrine in a concentration of 1:200,000 as effective in reducing blood in the operative field as epinephrine 1:50,000 when infiltrated into nasal tissue?

TECHNICAL APPROACH: Double blind, treatment arm trial of standard, in use procedures.

PROGRESS: No. of Subjects Enrolled - To Date: 84 Reporting Period:

Since the last report this study has been completed after studying 84 patients. It was found that the concentration of epinephrine did not significantly affect heart rate, blood pressure, blood loss, surgeon or patient satisfaction. Use of cocaine however was associated with lower blood loss, greater patient and surgeon satisfaction, and only modest increases in heart rates. This finished study has been submitted to the American Association of Nurse Anesthetists Journal for publication.

Detail Summary Sheet

Prot No: 29H89 Status: Completed

TITLE: Development of a Standard Technique of Insonation of the Umbilical Artery with Continuous Wave Doppler Ultrasound

Principal Investigator: MAJ Joseph P. Bruner, MC
Associate Investigators: CPT Thomas J. Luekehans, MC; CPT Beau J. Freund, MS
CPT Gregory Logsdon, MC

Department/Section: Obstetrics and Gynecology/Perinatology Service

Key Words: doppler ultrasonography;

Funding: FY 89: NA FY 90: NA Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: The purpose of the present study is to determine a standard technique for measuring the umbilical artery during pregnancy with continuous wave Doppler ultrasound.

TECHNICAL APPROACH: FVW SID ratio of placental cord insertion site, midcord regiment, and abdominal cord insertion site measured with duplex Doppler in radiology. Examination follows immediately in OB/GYN clinic with continuous wave Doppler machine, measuring easiest site, next easiest site, etc, until all 4 quadrants sampled. Analysis of correlation will follow.

PROGRESS: No. of Subjects Enrolled - To Date: 35 Reporting Period: Aug 90

Study completed, data review in progress.

Detail Summary Sheet

Prot No: 47H88 Status: Completed

TITLE: Uterine and Umbilical Artery Blood Flow Chart in Cesarean Section Under Subarachnoid Block

Principal Investigator: MAJ Joseph P. Bruner, MC
Associate Investigators: COL Kunio Miyazawa, MC

Department/Section: Obstetrics and Gynecology

Key Words: subarachnoid blood;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: The purpose of the present study is to measure changes in uterine and umbilical artery blood flow velocity waveforms that occur during administration of subarachnoid block in doses adequate to perform delivery be cesarean section. Conduction anesthesia is commonly employed for obstetric pain relief. The anesthetic agents used can be sympatholytic, however, and thus effect resting vascular tone.

TECHNICAL APPROACH: All patients admitted to the labor floor for scheduled repeat Cesarean section under subarachnoid block will be eligible to participate in the study. Data descriptive of the patient population and anesthesia procedure will be collected. Subarachnoid block will be administered according to established protocol and observing recognized guidelines of intravenous access, fluid volume preload, maintenance of physiologic blood pressure, and left uterine displacement. Baseline uterine and umbilical artery flow velocity waveforms will be recorded after the fluid load, and again after an anesthetic level of T_{10} to L_4 has been obtained.

PROGRESS: No. of Subjects Enrolled - To Date: 15 Reporting Period: Aug 90

Study completed, Data review in progress.

Detail Summary Sheet

Prot No: 48H88 Status: Terminated

TITLE: Continuous Instantaneous Assessment of the Adequacy of Fetal Cerebrovascular Perfusion by Means of Transvaginal Continuous Wave Doppler Ultrasonography of the Fetal Anterior Cerebral Arteries Through the Anterior Fontanelle

Principal Investigator: MAJ Joseph P. Bruner, MC
Associate Investigators: COL Kunio Miyazawa, MC

Department/Section: Obstetrics and Gynecology

Key Words: fetal anterior cerebral arteries;

Funding: FY 89: NA FY 90: NA Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: The purpose of the present study is: (1) to determine the feasibility of continuous transvaginal Doppler ultrasonography of the fetal anterior cerebral arteries during labor and delivery; (2) to determine the best means of fetal anterior cerebral artery waveform analysis for clinical applications; (3) to correlate recorded flow velocity waveforms with methods of intrapartum fetal surveillance currently in use; (4) to assess the desirability of developing a prototype for an integrated Intrapartum Fetal Surveillance Monitor.

TECHNICAL APPROACH: After cerebral artery flow velocity wave forms measured manually during labor, delivery and the neonatal period and compared to known standards.

PROGRESS: No. of Subjects Enrolled - To Date: 5 Reporting Period: Aug 90

Study discontinued, investigator leaving.

Detail Summary Sheet

Prot No: 34H88 Status: Ongoing

TITLE: A Prospective Evaluation of Laparoscopic Techniques Verres Needle Insufflation vs. Direct Trocar Insertion

Principal Investigator: CPT John W. Byron, MC
Associate Investigators: CPT Glenn R. Markenson, MC;
MAJ Milo L. Hibbert, MC; COL Kunio Miyazawa, MC

Department/Section: Obstetrics and Gynecology

Key Words: laparoscopic techniques;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To compare the efficiency and safety between two laparoscopic techniques in a prospective manner. Determine if direct insertion technique offers benefits of decreased time of surgery and reduction in amount of pneumoperitoneum required.

TECHNICAL APPROACH: Patients for the proposed study will come from those undergoing laparoscopic procedures through any of the gynecologic teams: GYN Oncology Team, GYN Team, Family Planning or Infertility Service. Informed consent will be obtained prior to the procedure. Patients will then be randomized into one of the two groups with the procedure to be performed located on the surgeon data sheet. The data sheet will remain sealed until immediately prior to surgery. A data sheet will be completed by the operating surgeon in conjunction with the anesthetist. Data sheets will then be collected by an author who will check them for accuracy and completeness.

PROGRESS: No. of Subjects Enrolled - To Date: 200 Reporting Period: 200

Study was performed from September 1988 through June 1989 with over 200 patients enrolled. Results to be analyzed at this point. May possibly extend enrollment if necessary with CPT Glenn R. Markenson/MAJ Milo L. Hibbert, MC continuing in my place, after I PCS this summer.

Detail Summary Sheet

Prot No: 4H90 Status: Terminated

TITLE: Extended Preinduction Cervical Ripening Using Prostaglandin E_2 (PGE_2) Intracervical Gel; A Randomized Clinical Trial

Principal Investigator: CPT Joseph Gass, MC
Associate Investigators: MAJ Joseph Bruner, MC

Department/Section: Obstetrics/Gynecology

Key Words:

Funding: FY 89: NA FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Terminated

OBJECTIVE: To assess the efficacy of PGE_2 intracervical gel as cervical ripening agent when administered repetitively over an extended period of time.

TECHNICAL APPROACH: Study candidates will be selected from the TAMC high risk obstetric service and will satisfy preselected criteria. Candidates will be randomized to a study or control group. Study and control groups will be compared with regard to change in Bishops score, length of labor, incidence of complications, mode of delivery, gestational age at delivery, length of postpartum stay and pregnancy outcome. Objective measurements of clinical efficacy will be analyzed by means of parametric and nonparametric tests of repeated measures.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period:

Effective March 1990, this clinical protocol had become standard practice. It was therefore decided to discontinue the study.

Detail Summary Sheet

Prot No: 35H89 Status: Completed

TITLE: Effect of Local Infiltration Anesthesia of Abdominal Incisions on Post-Operative Pain Relief and the Requirement for Post-Operative Pain Medication

Principal Investigator: CPT James W. Hubbard, MC
Associate Investigators: LTC J. Benjamin Hall, MC; MAJ Joseph P. Bruner, MC;

Department/Section: Obstetrics and Gynecology

Key Words: intra-operative infiltration;

Funding: FY 89: FY 90: $4,649 Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To evaluate the effect of incisional infiltration of bupivicaine versus normal saline infiltration vs. no treatment upon subjective perception of post-operative pain and the requirement for pain medication in women undergoing cesarean section.

TECHNICAL APPROACH: Patients are matched for 1) No treatment. 2) Infiltration with normal saline or 3) Infiltration with 0.25% Marcaine. Performed following closure of rectus fascia and prior to skin closure.

PROGRESS: No. of Subjects Enrolled - To Date: 63 Reporting Period: 63

Data collection complete.

Detail Summary Sheet

Prot No: 9H90 Status: Completed

TITLE: Evidence of acute cocaine and methamphetamine abuse in pregnant women presenting to labor and delivery

Principal Investigator: CPT Barry W. King, MC
Associate Investigators: MAJ Joseph P. Bruner, MC
MAJ Albert P. Sarno, MC; CPT John C. Moad, MC

Department/Section: Obstetrics and Gynecology

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: To determine the incidence of acute cocaine and methamphetamine abuse in patients presenting to TAMC Labor and Delivery for evaluation and whether there is a higher incidence of acute cocaine and methamphetamine abuse in patients presenting for evaluation of pre-term labor, vaginal bleeding or abruption.

TECHNICAL APPROACH: For a period of 30 days all patients presenting to the labor floor for evaluation will have a portion of their urine specimen placed in separate tubes. Specimens will remain anonymous but may be marked as follows:

P - if patient presents with evidence of preterm labor
B - if patient presents with evidence of bleeding
A - if patient presents with possible abruptions, all other specimens will be left blank

Specimens will be sent to the laboratory and held for later analysis. All specimens will be tested for cocaine metabolites (methyl ecgonine) and methamphetamines by established laboratory procedure.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Data collected. Positive results awaiting confirmation prior to write up of paper.

Detail Summary Sheet

Prot No: 23H90 Status: Ongoing

TITLE: A Prospective Randomized Blinded Trial of Indomethacin in Conjunction with Conventional Tocolytics as an Adjunct in the Treatment of Premature Labor

Principal Investigator: CPT Mark T. Lau, MC
Associate Investigators: MAJ Albert P. Sarno, MC; MAJ Jerome Kopelman, MC; COL Larry L. Morgenstern, MC

Department/Section: Department of Obstetrics & Gynecology

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To assess the safety and efficacy of indomethacin as an adjunct to conventional tocolytics in the treatment of premature labor in patients who have failed first line therapy.

TECHNICAL APPROACH: Candidates for study will be selected from women admitted to the TAMC and MAMC labor and delivery suites with the diagnosis of premature labor who fail conventional intravenous tocolytic therapy. Premature labor will be defined as documented cervical change with uterine contractions greater than 6 per hour. Conventional intravenous tocolytic therapy consists of ritodrine hydrochloride or magnesium sulfate. Patients eligible for study entry will be counseled regarding potential risks and benefits of participation as well as available alternatives. The gestational age range acceptable for the study will be 20 - 34 weeks.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New study, no subjects enrolled yet.

Detail Summary Sheet

Prot No: 27H90 Status: Ongoing

TITLE: Microheterogeneity of Human Chorionic Gonadotropin (hCG) in Ectopic Pregnancies

Principal Investigator: LTC Gerard S. Letterie, MC
Associate Investigators: John R. Claybaugh, PhD;
Catherine F.Y. Uyehara, PhD

Department/Section: Obstetrics and Gynecology

Key Words: serum human chorionic gonadotropin (hCG); ectopic pregnancies

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if unique variants of serum hCG exist in association with ectopic pregnancies (EP).

TECHNICAL APPROACH: An analysis of serum hCG concentrations and hCG microheterogeneity will be made on a single serum sample obtained during the first trimester from patients fulfilling the study criteria.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: 17H87 Status: Ongoing

TITLE: Comparison of Pregnancy Rates Using Oil-based and Water-based Contrast Medium in the Evaluation of Tubal Patency

Principal Investigator: MAJ Gerard S. Letterie, MC
Associate Investigators: COL Kunio Miyazawa, MC

Department/Section: Obstetrics and Gynecology

Key Words: tubal patency;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if the use of oil-based contrast medium in the evaluation of tubal patency enhances fertility when compared to water-based solutions.

TECHNICAL APPROACH: Sixty patients fulfilling the study criteria will be entered into one of two random study groups. Group I patients will have an oil-based contrast medium injected during the intra-operative tubal insufflation and a water based contrast medium will be used in an identical fashion on Group II patients. Effectiveness will be determined by the conception rates for the two groups at the end of a three month period.

PROGRESS: No. of Subjects Enrolled - To Date: 22 Reporting Period: 14

Thirty patients have been entered, fifteen into each of two groups (as described above). Six pregnancies in the oil-based group and one patient in the water-based group have been observed. This difference was statistically significant (Fisher's Exact Test). No adverse effects were noted. Preliminary manuscript is in preparation.

Detail Summary Sheet

Prot No: 29H87 Status: Ongoing

TITLE: Evaluation of Missed Pills on the Effectiveness of Oral Contraception

Principal Investigator: MAJ Gerard S. Letterie, MC
Associate Investigators: LTC James Wilson, MC

Department/Section: Obstetrics and Gynecology

Key Words: oral contraception;

Funding: FY 89: FY 90: $4,719 Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if missed pills in an oral contraceptive cycle result in the sequence of follicular maturation and eventual ovulation.

TECHNICAL APPROACH: Ten patients will be assigned to each group on a rotating basis for a total of 20 patients. The study population will consist of volunteers drawn from these patients referred to the Reproductive Endocrinology Service, Department of Obstetrics and Gynecology for tubal reanastomosis. The use of this specific population will enable a manipulation of an oral contraceptive regimen without the risk of pregnancy.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Eight patients have been entered. Results are preliminary. Study will be continued until a full complement of patients has been achieved. No adverse effects have been noted. Study is ongoing.

Detail Summary Sheet

Prot No: 4H89 Status: Ongoing

TITLE: A Prospective Evaluation of Serial Concentrations of Human Atrial Natriuretic Peptide (ANP), Plasma Renin Activity, and Aldosterone, in Normal Pregnancies, and Those at Risk for Preeclampsia

Principal Investigator: CPT Glenn R. Markenson, MC
Associate Investigators: MAJ Jerome Kopelman, MC; John Claybaugh, Ph.D.
CPT Beau J. Freund, MS; COL Kunio Miyazawa, MC

Department/Section: Obstetrics and Gynecology

Key Words: atrial natriuretic peptide (ANP);

Funding: FY 89: $5,011 FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: (1) To determine if ANP secretion is altered during pregnancy. (2) To determine the prognostic or diagnostic value for ANP in pregnancies complicated by preeclampsia. (3) To determine if there is an association between ANP, Plasma renin activity, and aldosterone in normal pregnancies and those complicated by preeclampsia.

TECHNICAL APPROACH: Patients at risk for preeclampsia are screened for blood pressure weight, plasma renin activity, aldosterone, and atrial natriuretic hormone at 14, 28, 36, 38, 40 weeks and 6 weeks post partum. Samples are obtained after the subjects are at rest - in the lateral recumbent position for 15 minutes.

PROGRESS: No. of Subjects Enrolled - To Date: 48 Reporting Period: 48

Total of 48 patients enrolled - 7 are unable to be studied (6 withdraw, 1 patients records in house were not available).

Findings - ANF increases prior to the diagnosis of preeclampsia - this increase correlated with the rise in Mean Arterial Blood Pressure. Both of these were stat significant. Trends of increases were noted in PRA & Aldo in normal pregnancies, trends in suppression were noted in preeclamptic pregnancies (not significant). PRA was significantly decreased in pre-eclamptic pregnancies C/W chronic hypertensive pregnancies perhaps providing a means to differentiate between chronic HTN and preeclampsia.

Detail Summary Sheet

Prot No: 29T86 Status: Terminated

TITLE: GYN-Surgical Training Laboratory Using Animal Models (Swine)

Principal Investigator: COL Kunio Miyazawa, MC
Associate Investigators:

Department/Section: Obstetrics and Gynecology/Gynecology Oncology

Key Words: training

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: To expose TAMC gynecology residents to procedures performed in the management of gynecologic malignancies and to train them in the management of minor urologic and intestinal complications during gynecologic surgery.

TECHNICAL APPROACH: Pigs will be preanesthetized with Acepromazine, 0.2 mg/kg IM, and Atropine, 0.04 mg/kg IM; sedated with Ketamine HCl, 22 mg/kg IM; and then either (1) anesthetized with sodium pentobarbital IV to effect with additional pentobarbital given as needed to maintain a surgical plane of anesthesia, or (2) anesthesia induced with sodium pentothal and maintained with nitrous oxide and methoxyflurane. All animals will be intubated. All animals will be euthanized at the end of the laboratory so no postoperative medication is necessary.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Due to the significant enhancement training program for OB/GYN resident staff regularly held by HSC, this program will be terminated to incorporate a centralized Army (military) training.

Detail Summary Sheet

Prot No: 3H89 Status: Terminated

TITLE: Chorionic Villous Sampling in a Military Population

Principal Investigator: MAJ Albert Sarno, MD
Associate Investigators: MAJ Jerome N. Kopelman, MC

Department/Section: Obstetrics and Gynecology

Key Words: (CVS);

Funding: FY 89: NA FY 90: NA Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: The purposes of this project are: (1) to compare the efficiency of ultrasonically directed transabdominal needle biopsy of chorionic villi to midtrimester genetic amniocentesis; (2) to compare the efficiency of obtaining chromosome preparations which are suitable for clinical laboratory testing from these samples.

TECHNICAL APPROACH: Patients with requirement for early prenatal diagnosis or need for large tissue sample candidates for CVS. Specimens obtained under ultrasound guidance and processed at Vivingen, Santa Fe, NM. Details of clinical course, specimen collection, antepartum care, delivery and neonatal examination collected and compared to midtrimester amniocentesis and early aminiocentesis. Data collection coordinated with tissue lab at Vivigen.

PROGRESS: No. of Subjects Enrolled - To Date: 5 Reporting Period: Aug 90

1 July 1989 - 30 June 1990 - 14 studies. All studies performed in first and second trimesters for prenatal diagnosis in living fetuses. Three (3) karyotypes abnormal. Unable to confirm diagnosis because patients terminated to civilian facilities. All fetuses with normal karyotypes live birth at term. All neonates normal, no complications noted.
Discontinue as Clinical Investigation protocol. Transfer to genetic QA program.

Detail Summary Sheet

Prot No: 60H88 Status: Completed

TITLE: Relief of Repetitive Variable Decelerations by Saline Amnioinfusion in Conjunction with Amniotic Fluid Index Determinations

Principal Investigator: CPT Jane Shen-Gunther, MC;
Associate Investigators: COL Kunio Miyazawa, MC; MAJ Jerome Kopelman, M.C.

Department/Section: Obstetrics and Gynecology

Key Words: amnioinfusion

Funding: FY 89: NA FY 90: NA Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To determine the success rate of amnioinfusion for complete relief of repetitive moderate and severe variable decelerations in conjunction with AFI determinations. To determine the minimum amniotic fluid index achieved by amnioinfusion which will result in complete relief of repetitive variable decelerations. To compare the following outcomes between the infusion-successful and nonsuccessful groups (after segregating the nulliparous and multiparous groups): 1) mode of delivery: vaginal vs. cesarean 2) cesarean section indicated for fetal distress 3) incidence of cord complications: No cord complications vs. identified nuchal cords, occult cord, bandilard cord, true knot; 4) arterial and venous cord PH results 5) APGAR scores

TECHNICAL APPROACH: After meeting the inclusion criteria, the patient's consent is obtained, and fetal scalp electrode and intrauterine catheter are placed. The preinfusion amniotic fluid index is determined by ultrasound and reassessed every 30 minutes while the infusion is running. A final AFI is determined upon reaching therapeutic success. Amnioinfusion is performed by using normal saline in IV bags and connecting it to the intrauterine catheter by IV tubing and infusing the fluid at the rate of 1000 cc/hr. If fetal distress develops, management is based on scalp pH results. The maximum allowable AFI is set at 20 to prevent the rare complication of polyhydramnios.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: 23

Investigation was completed in January 1990, paper to be completed in near future.

Detail Summary Sheet

Prot No: 39H89 Status: Completed

TITLE: Prevalence of Cytomegalovirus (CMV) Antigenemia in Tripler Army Medical Center Random Blood Donors

Principal Investigator: CPT Randy Hamill, MC
Associate Investigators: Dr. Lucille Kimura, Ph.D., 1LT Frank Cross, MC; LTC David Posey, MC

Department/Section: Pathology and Area Laboratory Services

Key Words: cytomegalovirus (CMV); antigenemia;

Funding: FY 89: NA FY 90: NA Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To determine the prevalance of CMV antigenemia and therefore potential CMV infectivity of random donor blood units. Compare the prevalance of CMV antigenemia to the prevalence of CMV seropositivity in random donors.

TECHNICAL APPROACH: The donor center of the TAMC blood will collect one green top tube of blood (7-10 ml with sodium heparin) from random consenting donors during blood drives. At least 200 samples will be collected. These samples will be taken to he TAMC hematology lab where they will be processed that same day for CMV antigen testing. Simultaneously, CMV antibody testing will be performed by the blood bank on a separate sample of blood as part of the routine screening of donor units.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Only 150 samples were collected. Collection and testing of samples has been completed. No positive antigen samples were found, which most likely indicated a lack of sensitivity of the test. We are still considering writing the paper even though the objectives were not met.

Detail Summary Sheet

Prot No: 21H88 Status: Completed

TITLE: Use of Maternal Serum IgG Antibody Titer as an Assessment of the Risk of Infection with Herpes Simplex Virus (HSV) to the Unborn Infant

Principal Investigator: COL Robert B. Hill, MC
Associate Investigators: CPT Beau J. Freund, MS; COL Kunio Miyazawa, MC: MAJ Jerome N. Kopelman, MC; COL Joseph C. Woods, MC; CPT Kraig S. Lerud, MC; Patricia S. Toyama, M.S.

Department/Section: Pathology and Area Laboratory Services

Key Words: maternal serum igG antibody titer; herpes simplex virus (HSV);

Funding: FY 89: NA FY 90: Periodic Review Date: Sep 90
Gifts: *$85,639. Decision: Completed

OBJECTIVE: The primary objective of this project is to test the possibility that obstetricians may be able to simplify their management of patients with herpes simplex virus infection during pregnancy. Instead of cumbersome culturing procedures, results from this project may provide evidence that ordering two sequential herpes serologies during the course of the pregnancy may provide an alternative and easier method of predicting the susceptibility of an infant to herpes neonatorum based on maternal antibody status.

TECHNICAL APPROACH: Laboratory quality assurance study.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

This study has been completed and no further specimen collection is necessary.

Detail Summary Sheet

Prot No: 50H89 Status: Completed

TITLE: The Prevalence of Hepatitis A and Hepatitis Non-A, Non-B Antibodies in the Population of American Samoa

Principal Investigator: COL Robert B. Hill, MC
Associate Investigators: MAJ Lawton A. Seal, Ph.D., MS;
MAJ Mike Langford, DVM; Arwind R. Diwan, Ph.D.

Department/Section: Pathology and Area Laboratory Services

Key Words: Hepatitis A; Hepatitis Non-A; Hepatitis Non-B;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To determine the prevalence of antibodies of the Hepatitis A virus (HAV) and the Non-A, Non-B hepatitis (NANBH) virus(es) in this relatively static population of Pacific Islanders.

TECHNICAL APPROACH: As all the sera for this study has been collected previously by others, no additional serum will be collected, and no other patients will be enrolled in this study. A representative sample of 4,000 - 5,000 sera under evaluation for hantavirus antibodies will be used in these studies. Antibody determinations will be via standard elisa assays presently available or under development by Abbott Diagnostics and we will follow the manufacturer's guidelines for all test procedures. Multiple logistical regression will be employed to evaluate the results.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

This study has been completed and no further specimen collection is necessary.

Detail Summary Sheet

Prot No: 30H88	Status: Completed
TITLE: Microtrak HSV Culture Identification Test Premarket Evaluation Trial	
Principal Investigator:	MAJ Lawton A. Seal, Ph.D., MS
Associate Investigators:	CPT Kathleen M. Fleet, MC; Ms. Patricia Toyama, M.S., COL Robert B. Hill, MC; COL Joseph C. Woods, MC
Department/Section: Pathology and Area Laboratory Services	
Key Words: HSV culture	
Funding: FY 89: FY 90 :	Periodic Review Date: Sep 90
Gifts:	Decision: Completed

OBJECTIVE: To compare the overall accuracy of the Microtrak HSV Culture Identification Reagent, using a centrifugation-enhanced shell via', to conventional cell culture methods in use at Tripler for identification of HSV antigen obtained from clinical specimens.

TECHNICAL APPROACH: Laboratory quality assurance study.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period:

Protocols No. 46H88 and No. 30H88 were merged. One hundred ninety-nine (199) samples were included in the final analysis. Results of this study will be published in Clinical Microbiology in the format of a manuscript. Results irdicate that conventional cell culture methods in use at Tripler are by far more sensitive than the DNA probe or SYVA Microtrak HSV Culture Reagent.

Detail Summary Sheet

Prot No: 33H89 Status: Ongoing

TITLE: Prevalence of Hantavirus

Principal Investigator: MAJ Lawton A. Seal, Ph.D., MS
Associate Investigators:

Department/Section: Pathology and Area Laboratory Services

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine the prevalence of Hantavirus antibody in human population groups located in the Pacific region.

TECHNICAL APPROACH: Serologic testing (EIA) for serum antibodies to the hantavirus (KHF).

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period:

(Repository sero samples of approximately 3,000.) The bulk of the sero testing has been completed. Samples were subjected to conservatory testing; we are awaiting the results of that testing. That part of the study is being done my MAJ Langford. CPT Glenn Sandberg, MC, will take over as principal investigator.

Detail Summary Sheet

Prot No: 44H87 Status: Completed

TITLE: An Investigation of the Possible Transmission of Hepatitis A by Transfusion of Infectious Blood Products at Tripler Army Medical Center

Principal Investigator: MAJ Lawton A. Seal, Ph.D. MS
Associate Investigators:

Department/Section: Pathology and Area Laboratory Services

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: To assay for the presence of hepatitis A virus (HAV) in blood products obtained from an infected donor and to monitor the status of the recipient of these potentially infectious products in regard to the presence of HAV specific antibodies (abs) or antigen (agn).

TECHNICAL APPROACH: Viral isolation and immunological assay of patient samples.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period:

Although the recipient of the potentially contaminated blood products was lost to followup at the 121st Evac Hospital upon her return to the ROK, hepatitis A virus particles were not found in the suspected HAV contaminated plasma by electron microscopic analysis. Attempts at culture are by ultracentrifugation techniques. These unusual findings are being reported in the June 90 issue of Military Medicine.

Detail Summary Sheet

Prot No: 46H88 Status: Completed

TITLE: Evaluation of the Pathogene Identification Kit - An in situ DNA Probe for Herpes Simplex Virus (HSV)

Principal Investigator: MAJ Lawton A. Seal, Ph.D., MS
Associate Investigators:

Department/Section: Pathology and Area Laboratory Services

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: To compare the sensitivity and specificity of this newly developed method of detecting HSV in clinical material to that of a standard culture method as outlined in TAMC Protocol No. 21H88 and a modified culture method as described in TAMC Protocol No. 30H88.

TECHNICAL APPROACH: Laboratory quality assurance study.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period:

Protocols No. 46H88 and No. 30H88 were merged. One hundred ninety-nine (199) samples were included in the final analysis. Results of this study will be published in Clinical Microbiology in the format of a manuscript. Results indicate that conventional cell culture methods in use at Tripler are by far more sensitive than the DNA probe or SYVA Microtrak HSV Culture Reagent.

Detail Summary Sheet

Prot No: 38H87 Status: Terminated

TITLE: A Comparison of Transdermal Estradiol and Oral Combined Estrogen-Progestin Preparations in the Treatment of Polycystic Ovarian Syndrome

Principal Investigator: COL Richard A. Banks, MC
Associate Investigators: MAJ Robert M. Lehman, MC;
MAJ Gerard S. Letterie, MC

Department/Section: Pediatrics

Key Words: polycystic ovarian syndrome;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Terminated

OBJECTIVE: To compare the effects of transdermal estradiol and oral sequential estrogen-progestin preparations in patients with polycystic ovarian syndrome, with emphasis placed on relief of symptoms and occurrence of side effects.

TECHNICAL APPROACH: Two-arm treatment trial of approved treatments.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Although intake studies have been initiated on several girls, the inability to guarantee birth control has prevented girls from entry into actual study phase. Please terminate this protocol.

Detail Summary Sheet

Prot No: 4H87 Status: Ongoing

TITLE: Immunosuppressive Therapy with Methylprednisolone, Prednisone, and Azathioprine in Patients with Newly Diagnosed Insulin-Dependent Diabetes Mellitus

Principal Investigator: COL Richard A. Banks, MC
Associate Investigators: Janel Silverstein

Department/Section: Pediatrics

Key Words: diabetes mellitus; pediatric; ketoacidosis;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Imuran Decision: Continue

OBJECTIVE: To prevent the progression of autoimmune destruction of the pancreatic islet β-cells in previously undiagnosed diabetic patients presenting with hyperglycemia but without overt ketoacidosis.

TECHNICAL APPROACH: Four randomly assigned treatment arms: 1) steroids and imuran 2) steroids 3) imuran and 4) neither steroids nor imuran; measured against multiple parameters of progression of diabetes.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Study is still in progress at Florida. No candidates have qualified in Hawaii for inclusion. Please continue protocol.

Detail Summary Sheet

Prot No: 9A89 Status: Ongoing

TITLE: Pediatric Intubation Training Utilizing the Feline Model

Principal Investigator: COL Richard A. Banks MC
Associate Investigators: COL John D. Roscelli, MC

Department/Section: Pediatrics

Key Words: intubation training;

Funding: FY 89: $3,071 FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: This training is designed to teach physicians and other health care professionals the basic knowledge and endotracheal intubation skills required to resuscitate a neonate (newborn) or infant.

TECHNICAL APPROACH: Initially the cats will be anesthetized with ketamine HCL (22 mg/kg intramuscularly) with atropine (0.04 mg/kg, subcutaneously). Additional doses of ketamine may be given if necessary by the Veterinarian staff. The administration and monitoring of the anesthesia will be directly performed by the Veterinarian staff. The students will then visualize the larynx and perform endotracheal intubation using the larynx scope and endotracheal tubes. Anesthesia will be maintained throughout the procedure. Examination gloves will be worn by the students. Animals not suffering significant trauma may be retained for future sessions. If euthanasia is required (determined by the Veterinarian staff), the animals will be euthanized with T-61 given IV, 0.3 ml/kg.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

The above protocol (#9A89) needs to be continued. Currently, no plans for Pediatric Advanced Life Support (PALS). The last course was March, 1989. However, there is a high likelihood that a PALS course will be held in FY91.

Detail Summary Sheet

Prot No: 31H85 Status: Ongoing

TITLE: Treatment of Kawasaki Syndrome with Intravenous Gamma Globulin

Principal Investigator: COL James W. Bass, MC
Associate Investigators: Marian E. Mellish, M.D.

Department/Section: Pediatrics

Key Words: Kawasaki syndrome

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: IV Gamma Globulin Decision: Continue

OBJECTIVE: To evaluate the use and establish the proper dose of intravenous Immuno Globulin for the treatment of children with Kawasaki Syndrome.

TECHNICAL APPROACH: Children with Kawasaki Syndrome seen at Tripler Army Medical Center will be offered the opportunity to participate in the study after informed written consent is obtained from the parents. The intravenous immuno globulin will be supplied by Dr. Mellish. It will be administered in two different doses as outlined in the protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Although this study has been in operation over the past 3 - 4 years and we have not entered a patient with Kawasaki's into it, we would like to keep it opened at least for the the next 1 - 2 years. We have had two patients with mild Kawasaki's Syndrome diagnosed too late to be entered into this study in the past year. But none with fully developed disease presenting within the first five days of their illness, and therefore candidates for gamma globulin therapy. This multicenter cooperative study has already shown that intravenous immunoglobulin given at 400 mg/kg/day for four days is dramatically effective in reducing the incidence of coronary aneurysms and infarctions. A more recent arm of the study has shown that a single does of 2 kg/per kilo is equally effective and it is also associated with dramatic immediate clinical improvement of the patient. Should a patient with Kawasaki's Syndrome present in the coming year, we would like to be able to enter this patient into the intravenous immunoglobulin treatment study with whatever arm of the protocol is current.

Detail Summary Sheet

Prot No: 33H87 Status: Ongoing

TITLE: Ceftriaxone vs. Augmentin for Initial Empirical Therapy of Occult Bacteremia

Principal Investigator: COL James W. Bass, MC
Associate Investigators:

Department/Section: Pediatrics

Key Words: occult bacteremia;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To evaluate the efficacy of a single intramuscular injection of ceftriaxone (75 mg/kg) versus augmentin suspension administered three times a day (40 mg/kg/day divided into three equal doses) in preventing or alleviating the acute infectious morbidity of occult bacteremia in febrile children.

TECHNICAL APPROACH: Children 3-36 months of age with documented rectal or tympanic temperature ≥103.0 and no source of infection by physical exam, chest x-ray, and lab (urinalysis) with informed consent will be randomized to receive empirical therapy of either oral Augmentin or one injection of IM Ceftriaxone. Patients are then followed up in 12-36 hours for evidence of focal infection and blood culture results.

PROGRESS: No. of Subjects Enrolled - To Date: 482 Reporting Period: 482

Four-hundred eighty-two patients have been enrolled in this study as of 31 October 1989. There have been 53 (11.0%) positive blood cultures. All children have done well and none have developed focal infections. This study is a multicenter study. It is anticipated that we will need over 1,000 patients entered into this study with approximately 100 positive blood cultures to prove or disprove our hypothesis - that Ceftriaxone will prove superior to Augmentin for patients with occult bacteremia. This will probably take another 1 - 2 years.

Detail Summary Sheet

Prot No: 23H88 Status: Ongoing

TITLE: Predicting Responsiveness to Methylphenidate

Principal Investigator: Dr. Thomas E. Gallagher, M.D.
Associate Investigators: Dr. David S. Weiss, Ph.D.

Department/Section: Pediatrics//Exceptional Family Member Program

Key Words: methylphenidate (ritalin);

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To identify the variables which predict the responsiveness of Attention Deficit Disorder children to treatment with methylphenidate (Ritalin).

TECHNICAL APPROACH: Multivariant prospective data collection of patient care.

PROGRESS: No. of Subjects Enrolled - To Date: 29 Reporting Period: 29

There are now 27 subjects enrolled, although data collection is not complete on all of them.

Detail Summary Sheet

Prot No: 61H89 Status: Ongoing

TITLE: Clinical Application of Orthostatic Measurements in Adolescents

Principal Investigator: CPT William Joseph Horam, MC
Associate Investigators: COL John D. Roscelli, MC; CPT Linda M. Brantner, MC

Department/Section: Pediatrics

Key Words: orthostatic measurements in adolescents

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: Establish normal standards of measurement for orthostatics in healthy adolescents and evaluate utilization of orthostatic measurements for ill adolescents.

TECHNICAL APPROACH: Prospective clinical study.

PROGRESS: No. of Subjects Enrolled - To Date: 127 Reporting Period: 127

Enrollment of subjects complete as of 25 May 1990; have begun initial work on paper.

Recipient of Kay Kyser Research Award, June 1990.

Abstract submitted for Pediatric Tri-Service Conference, March 1991.

Manuscript for publication pending following final revision a copy will be sent to clinical investigation.

Detail Summary Sheet

Prot No: 57H88 Status: Terminated

TITLE: Combined Utilization of Albuterol, Cromolyn Sodium and Prednisone in the Management of the Dual Phases of Acute Asthma

Principal Investigator: CPT Wm. Joseph Horam, MC
Associate Investigators: COL James W. Bass, MC;
Dr. Wallace J. Matthews, M.D.
CPT Mark E. Alexander, MC

Department/Section: Pediatrics

Key Words: acute asthma;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: To determine the clinical effectiveness of combining albuterol, cromolyn sodium and prednisone for the outpatient management of the early and late phases of acute asthma.

TECHNICAL APPROACH: Prospective clinical quality assurance study.

PROGRESS: No. of Subjects Enrolled - To Date: 16 Reporting Period: 16

Study terminated; logistically difficult to perform in our busy outpatient pediatric clinic by anyone other than principal investigator. I was unable to devote full time to the clinic because of other responsibilities as a resident.

Detail Summary Sheet

Prot No: 10H90 Status: Completed

TITLE: EXOSURF Pediatric Sterile Powder Treatment IND Protocol, EXO-501

Principal Investigator: MAJ Robert V.Jarrett
Associate Investigators:

Department/Section: Pediatrics/Neonatology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: The purpose of this treatment IND was to make EXOSURF available for infants with confirmed Respiratory Distress Syndrome or at risk of developing RDS for whom no satisfactory alternative treatment exists and to monitor for serious unexpected adverse events prior to general marketing of the drug.

TECHNICAL APPROACH: EXOSURF administered in the following situations after informed consent:

1) Single dose of 5ml/kg intratracheal in infants with birthweight 700 -1100 grams prophylactically in delivery room.

2) Two doses, twelve hours apart, between 2 - 24 hours age in infants with birthweight 700 - 1350 grams with confirmed RDS.

3) Two doses, twelve hours apart, between 2 - 24 hours age in infants with birthweight greater than 1350 grams with confirmed RDS.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

This study is now complete. Twelve infants were enrolled at TAMC. Eleven had positive clinical responses to EXOSURF. One infant developed a pulmonary hemorrhage following EXOSURF administration and died. EXOSURF has been released for use by the FDA.

Detail Summary Sheet

Prot No: 18H89 Status: Completed

TITLE: EXOSURF Pediatric Multiple Dose Prophylaxis Study in High Risk Premature Infants: A Multicenter Trial (P51 Protocol 13)

Principal Investigator: LTC Robert V. Jarrett, MC
Associate Investigators: MAJ Thomas J. Kueser, MC;
MAJ William M. Southgate, MC;
MAJ Maureen Jewitt, AN

Department/Section: Pediatrics/Neonatology Service

Key Words: EXOSURF; prophylaxis;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: To study the efficacy of three artificial surfactant treatment regimens in the prophylactic treatment of premature infants with birth weights between 700 and 1100 grams.

TECHNICAL APPROACH: This is a multicenter study plan to enroll 768 patients, with at least 10 patients at TAMC. The effects of two dosage regimens of EXOSURF Pediatric will be studied. Each dosing regimen consists of three intratracheal doses of either EXOSURF Pediatric or air given 12 (±1) hours apart to infants with birthweights between 700 and 1100 grams. The first dose will be immediately after the infant is stabilized at birth. Patients in Group A will receive three 5cc/kg EXOSURF Pediatric followed by two 5cc/kg doses of air. Patients in Group C will receive three 5cc/kg doses of EXOSURF Pediatric. This protocol may be modified by the results of another multicenter EXOSURF protocol (Protocol 04). In that protocol infants with birthweights between 700 and 1100 grams are randomized to receive a single prophylactic dose 5cc/kg of EXOSURF Pediatric or air at birth. If a single dose of EXOSURF Pediatric proves efficacious, patient entry in Group A of this study will be halted. If it does not prove effective in improving the incidence of intact cardiopulmonary survival, but other important clinical benefits are apparent, patients will continue to be enrolled in Groups A, B, and C. If no benefit is apparent from a single prophylactic dose, Group B will be dropped from this study.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Completed study. We entered one patient in this collaborative study. He did well. EXOSURF has been released for general use by FDA.

Detail Summary Sheet

Prot No: 19H89 Status: Completed

TITLE: EXOSURF Pediatric Dose and A-a Gradient Changes in Larger Infants with RDS (P51 Protocol 12)

Principal Investigator: LTC Robert V. Jarrett, MC
Associate Investigators: MAJ Thomas J. Kueser, MC;
MAJ William M. Southgate, MC;
MAJ Maureen Jewitt, AN

Department/Section: Pediatrics/Neonatology Service

Key Words: EXOSURF; respiratory distress syndrome(RDS)

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: The objectives of this study is premature infants with birthweight greater than 1250 grams and established RDS are to evaluate whether a 50% increment or decrement in EXOSURF Pediatric alters the effects of two 5cc/kg doses given 12 hours apart.

TECHNICAL APPROACH: This is a multicenter study plan to enroll 240 patients, with at least 10 patients at TAMC. The effects of three dosage regimens of EXOSURF Pediatric will be studied. Each dosing regimen consists of two intratracheal doses of either EXOSURF Pediatric or air given 12 (±1) hours apart to infants with birthweights greater than 1250 grams and established RDS. The first dose will be given after 2 hours of life but before 24 hours of life. Patients in Group A will receive two 5cc/kg doses of air. Patients in Groups B, C, and D will receive two 2.5cc/kg, 5.0 cc/kg, and 7.5 cc/kg doses of EXOSURF Pediatric, respectively, 12 hours apart.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Three infants were enrolled in this multicenter study. All did well. There were no adverse sequelae. Study is complete. EXOSURF has been released for general use by FDA.

Detail Summary Sheet

Prot No: 26H88 Status: Completed

TITLE: Vancomycin Dosing Based on Individual Pharmacokinetic Profiles in Neonates

Principal Investigator: LTC Robert V. Jarrett, MC
Associate Investigators: MAJ Thomas J. Kueser, MC; CPT Everett L. Gayle, MC
COL James W. Bass, MC

Department/Section: Pediatrics/Neonatology Service

Key Words: vancomycin; pharmacokinetic profiles;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To determine if vancomycin dosing based on individual pharmacokinetic profiles reliably effects desired therapeutic blood levels in neonates.

TECHNICAL APPROACH: Clinical quality assurance study of blood levels to pharmakokinetic profiles. Only modification made in approach has been to have pharmacy to suply all vancomycin doses in a unit dose form rather than have nursing draw up doses.

PROGRESS: No. of Subjects Enrolled - To Date: 14 Reporting Period: 14

Study completed. A total of 14 infants enrolled. 9/14 peak values were in desired range. 13/14 trough values in desired range. No long term adverse sequelae. Methodologic errors accounted for two failures. Conclusion: This method is as good as current published vancomycin dosing guidelines. Manuscript is in preparation.

Detail Summary Sheet

Prot No: 1H89 Status: Completed

TITLE: A Comparison of Liquid Nitrogen and Cantharidin in the Treatment of Warts in Children

Principal Investigator: CPT Peter E. Knott, MC
Associate Investigators: LTC, Bruce A. Cook, MC

Department/Section: Pediatrics

Key Words: cantharidin;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To compare the effects of liquid nitrogen and cantharidin in treating common warts with regard to: efficacy, time to resolution, and side effects.

TECHNICAL APPROACH: Patients age 0-18 years old with more than one common wart are treated with both liquid nitrogen and cantharidin. They are followed at weekly intervals to assess efficacy of treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 38 Reporting Period: 38

To date 38 patients have been entered into this study. The present plan is to enroll a total of 50. Liquid nitrogen appears to be superior to Cantharidin at this time but additional patients will be needed. Liquid nitrogen appears to be superior therapy for initial treatment of smaller warts. Manuscript is in preparation.

Detail Summary Sheet

Prot No: 44H89* Status: Ongoing

TITLE: National Survey of Pediatric Sedation Procedures

Principal Investigator: CPT Simone Nomizu, MC
Associate Investigators: COL James W. Bass, MC; CPT Mark Alexander, MC

Department/Section: Pediatrics

Key Words: sedation;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To collect data from institutions across the country through questionnaire form regarding the procedures used in the sedation of pediatric patients for diagnostic procedures.

TECHNICAL APPROACH: Questionnaires will be sent to various medical centers in order to collect the following data:

a. selection, route, and dosage of premedication
b. procedures for which sedation routinely used
c. age at which sedation routinely used
d. monitoring procedures
e. type of health care facility and practice
f. existence of written guidelines for pediatric sedation
g. approximate incidence of adverse side effects due to sedation

The date collected will be combined, analyzed and summarized; appropriate conclusions will be made in regards to a national consensus (if one does exist) as to the procedures used in the sedation of pediatric patients for diagnostic procedures. Also, further recommendations will be made for improving currently followed sedation protocols.

PROGRESS: No. of Subjects Enrolled - To Date: 82 Reporting Period: 82

*Exempt cmte/HUC review

To date over 82 questionnaires have been received. We are presently totaling the results. We expect to have this work finalized and ready to submit for presentation and publications with the next 2-3 months.

Manuscript is in preparation.

Detail Summary Sheet

Prot No: 16H89 Status: Ongoing

TITLE: Urinary C-peptide Response to Umbilical Arterial Catheter Position in Neonates

Principal Investigator: CPT Ronald D. Prauner, MC
Associate Investigators: LTC Robert V. Jarrett, MC; COL Richard A. Banks, MC
CPT Richard T. Hatch, MC; CPT Jeffery L. Maxey, MC

Department/Section: Pediatrics

Key Words: umbilical arterial catheter (UAC)

Funding: FY 89: NA FY 90: NA Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if umbilical Arterial Catheter (UAC) position, (high vs. low) results in different rates of insulin production in neonates.

TECHNICAL APPROACH: All infants in which a UAC is to be placed will be eligible for enrollment in the study. The decision to place a UAC will be made based solely on the infant's clinical condition. Informed consent will be obtained prior to enrollment of all infants. After enrollment, UAC placement will be allocated to either high or low position. The patients will be stratified based on weight. The first child in any weight group will have a high UAC tip placement. Subsequent UACs in each weight group will be alternated sequentially in order to maintain equal numbers of high and low UACs in each weight group. Each child will receive IV fluid (D10W) at 80 cc/kg/day (5.55 mg of glucose/kg/min). At 24 hours following placement of the catheter, a 4-6 hour collection of urine will be assayed for C-protein. The urine will be obtained by passive collection with a container placed to catch the urine as the child voids. Capillary dextrosticks will be obtained at a minimum of eight hour intervals during the first 24 hours following placement (as per NICU protocol). The study group will consist of 10 children with low UACs, 10 children with high UACs and 10 children receiving IVF through peripheral veins. Children enrolled in the study will be at no additional risk based on the study. Benefits of being enrolled in the study include prompt-recognition of problems involving glucose metabolism, as well as catheter related complications.

PROGRESS: No. of Subjects Enrolled - To Date: 10 Reporting Period: Jun 90

We plan to enroll 20 patients. No data as yet; waiting for sufficient number of samples to run simultaneously at Endocrine Sciences.

Detail Summary Sheet

Prot No: 25H90 Status: Ongoing

TITLE: A Prospective Controlled Trial of Trimethoprim-Sulfamethoxazole versus Cephalexin for Treatment of Cat Scratch Disease in Children

Principal Investigator: MAJ Judy Vincent, MC
Associate Investigators: LTC Bruce Cook, MC; CPT Martin Weisse, MC; CPT Cheryl Sisler, MC; MAJ Ronald Jones, MC; Debora Schotik, B.S.; COL Donald Person, MC; COL James W. Bass, MC

Department/Section: Department of Pediatrics

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine whether trimethoprim-sulfamethoxazole accelerates the resolution of symptoms and/or physical findings in cat scratch disease in children compared to cephalexin.

TECHNICAL APPROACH: Patients will be enrolled if they meet certain criteria predetermined by the principal investigator. A history and physical exam, laboratory, and radiologic exams will be performed. Patients will be randomized to receive one of two drug therapies and will be seen in the pediatric clinic once a week for a follow-up exam by either the principal investigator or one of the associate investigators as well as an ultrasound to assess the patient's lymph nodes. TAMC will process all lab specimens except for the antibody serology. CSD antibody serology will be performed by the CDC in Atlanta.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start. No progress to report.

Detail Summary Sheet

Prot No: 14H90 Status: Ongoing

TITLE: Efficacy of Cholestyramine in Acute Diarrhea in Children

Principal Investigator: CPT Martin E. Weisse, MC
Associate Investigators: Debora Schotik, Ph.D.

Department/Section: Pediatrics

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To assess cholestyramine vs. placebo in young children with diarrhea. Weight loss/gain, duration of diarrhea will be assessed.

TECHNICAL APPROACH: Two groups of patients will be assessed; treatment and placebo. Patients will be randomly assigned.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period: thru 9/90

The material with which to make the placebo just arrived ten days ago. As soon as it is mixed, we will commence enrollment of patients.

Detail Summary Sheet

Prot No: 3H90 Status: Ongoing

TITLE: The Prevention of Amphotericin B Nephrotoxicity With Intravenous Saline

Principal Investigator: CPT Martin Weisse, MC
Associate Investigators:

Department/Section: Pediatrics

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To assess onset, severity and incidence of renal toxicity in patients receiving amphotericin. Treatment group will receive NS bolus before and after amphotericin. Control group will receive standard therapy.

TECHNICAL APPROACH: Two groups, one control, one treatment with NS. Patients randomly assigned. Urine and serum electrolytes, creatinine, BUN assessed.

PROGRESS: No. of Subjects Enrolled - To Date: 5
Reporting Period: thru 9/90

Detail Summary Sheet

Prot No: 26D84 Status: Ongoing

TITLE: Use of Sodium Allopurinol to Control Hyperuricemia in Patients With No Therapeutic Alternative

Principal Investigator: CPT Scott C. Martin, MS
Associate Investigators: COL Jeffrey L. Berenberg, MC; LTC Bruce A. Cook, MC; LTC William J. Uphouse, MC; CPT Paul Fishkin, MC

Department/Section: Pharmacy Service/Oncology

Key Words: hyperuricemia; allopurinol;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Allopurinol Decision: Continue

OBJECTIVE: To provide a water soluble form of allopurinol that can be given intravenously to patients with hyperuricemia who are too ill to take oral medication.

TECHNICAL APPROACH: This is a "convenience" protocol to make an uncommonly required dosage form available for use without the need for individual, special exception approval of the committee for each patient. This study also centralizes and simplifies the procedures for requesting the drug for patients. It is anticipated that 1-2 patients a year will be treated on this protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 12 Reporting Period: 1

One patient enrolled in FY90. Protocol to continue as a "convenience protocol" for use on an as needed basis. Status is ongoing.

Detail Summary Sheet

Prot No: 15H89 Status: Ongoing

TITLE: A Study of the Relationship Between the Topography of Herniated Lumbar Disks, Lumbar List, and the Side of Pain

Principal Investigator: LTC Richard C. Schreck, SP
Associate Investigators: MAJ Kevin Foley, MC; MAJ Douglas Fellows, MC; Mark Laslett, N.Z.R.P.; Maynard Williams, M.S.C.

Department/Section: Physical Medicine

Key Words: herniated lumbar disks;

Funding: FY 89: $180 FY 90: Periodic Review Date: SEP 90
Gifts: Decision: Continue

OBJECTIVE: 1) To test the hypothesis that the relationship between an entrapped lumbar nerve root and a herniated lumbar disk will determine whether a lumbar list will be towards or away from the side of pain. Specifically: that a herniated disk that lies medial to the nerve root will cause a list to the same side as the pain, and a herniated disk that lies lateral to the nerve root will cause a list away from the side of pain. 2) To test the reliability and specificity with which therapists observe a lumbar list.

TECHNICAL APPROACH:

A. INCLUSIONS:
   1) Consecutive patients diagnosed as having a herniated lumbar disk.
   2) Those patients who are scheduled to undergo surgery for removal of the herniated lumbar disk.

B. EXCLUSIONS:
   1) Those who will not sign a standard informed consent form.
   2) Those patients who are unable (for whatever reason) to complete the study procedures.
   3) Those whose pain is too severe for them to be subjected to the study procedures.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

The number of subjects enrolled in the study as of 30 Sep 90 is 47. There have been 50 subjects asked to participate in the study with three patients electing not to participate. Of the 47 patients in the study, all have completed the procedures with no adverse response.

Early statistical analysis indicates that there is no correlation between the side of pain, lumbar list, and the location of the disk herniation. There have been no formal presentations of the data or articles written or published. Statistical analysis is being completed. We do not expect to enroll anymore subjects in the study. Submission of the study for publication is planned but the paper has not been written.

Detail Summary Sheet

Prot No: 59A88 Status: Terminated

TITLE: Resistance of Aedes albopictus in Hawaii to Mosquito Adulticides

Principal Investigator: LTC Bruce M. Furlow, MS
Associate Investigators: Mr. Brian Zeichner, U.S. Army Environmental Hygiene Agency (USAEHA), Aberdeen Proving Ground, MD.

Department/Section: Preventive Medicine Service

Key Words: mosquito; pesticides; Aedes albopictus;

Funding: FY 89: $372 FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: Determine the mortality response of Aedes albopictus mosquito populations to pesticides commonly used in Hawaii.

TECHNICAL APPROACH: Laboratory rat will be anesthetized, hair clipped from a 2" by 5" area of the back, and the animal will be placed in a net sling over a mosquito colony. Hungry, host-seeking female mosquitoes will take a blood meal. The rat will be exposed to mosquitoes until they are satiated and no more mosquitoes are observed feeding up to a maximum of 60 minutes. The rat will be removed and euthanized. The mosquitoes will be provided time for incubation of eggs and appropriate site for deposition of eggs.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Due to the departure of the principal investigator, LTC Bruce Furlow, this protocol was terminated.

Detail Summary Sheet

Prot No: 8H88 Status: Completed

TITLE: Measles Susceptibility in Hospital Personnel

Principal Investigator: MAJ Lorrin Pang, MC
Associate Investigators: MAJ Lawton Seal, MC; COL Joel Brown, MC; MAJ Merle Sprague, MC; MAJ Philip Bruno, MC

Department/Section: Preventive Medicine Service

Key Words: measles;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: Determine adequacy of ACIP screening (historical) procedure for determination of measles immunity in hospital staff. Also, prevalence of measles immunity in hospital staff will be determined.

TECHNICAL APPROACH: ACIP screening questionnaires are given to newly hired hospital staff. A sensitive and specific ELISA test for measles antibody is simultaneously done on a serum sample to determine accuracy of ACIP criteria.

PROGRESS: No. of Subjects Enrolled - To Date: 100 Reporting Period: 100

One hundred subjects were enrolled in this study. No additional subjects will be enrolled in this study. Data is currently being analyzed.

Detail Summary Sheet

Prot No: 37H89 Status: Ongoing

TITLE: The Effectiveness of a Community Health Nursing Outreach Program on Reducing the Effect of High-Risk Factors Associated with Child Abuse/Neglect

Principal Investigator: Teena Edwards, RN, MS
Associate Investigators: COL Lucille A. Smith, AN

Department/Section: Preventive Medicine Service/Community Health Nursing

Key Words: child abuse/neglect

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: This study will determine the correlation between a community health nursing outreach program and the effects of high-risk factors predisposing to child abuse/neglect within a military community.

TECHNICAL APPROACH: The protocol for this study has remained unchanged. However, because of a greater than 50% staff turnover, lack of staff resources for over a 4-month period, and new staff orientation, the program guidelines have not been strictly adhered to. Therefore, the study period has been delayed by six months.

PROGRESS: No. of Subjects Enrolled - To Date: 1001 Reporting Period: 100

One-hundred families are enrolled in this study as of 30 September 1990. Completion of research study is projected for December 1990, with analysis of data early January 1991.

Detail Summary Sheet

Prot No: 51H89* Status: Completed

TITLE: The Effect of the Absence of Father on the Patterns of Cosleeping in Military Families in Clinical and Nonclinical Samples

Principal Investigator: CPT John F. Forbes, MC
Associate Investigators:

Department/Section: Psychiatry

Key Words: cosleeping;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: It is hypothesized that there will be significant differences between the changes in the frequency and pattern of cosleeping in "clinical" vs. "nonclinical" military families. I expect to demonstrate a significantly larger proportion of cosleeping during father's absence in the clinical sample.

TECHNICAL APPROACH: To address the question, "does cosleeping cause psychiatric difficulties?" I propose to administer the accompanying questionnaire to parents visiting the Child and Adolescent Psychiatry and Pediatrics Clinic. The questionnaire will explore sleeping habits in military families during times of father's deployment and of father's presence at home. The questionnaires will be anonymous. I will be present in the Pediatrics Clinic to hand out the questionnaires and to answer questions. Those questionnaires administered to parents of the Child and Adolescent Psychiatry Clinic will be mailed out with our other questionnaire in the intake packet, or given to parents by their clinicians. In addition to the questions regarding sleep habits, the questionnaire will have several questions screening for a history of psychiatric treatment or psychiatric problems in the child, Using the responses to these questions, the questionnaires will be sorted into two groups: one with clinical symptoms or presentations, and the other, the control or "healthy" group.

PROGRESS: No. of Subjects Enrolled - To Date: 52 Reporting Period: 52

Parents completed the questionnaire involved in this survey study regarding the frequency and circumstances of cosleeping (children sleeping in the parents' bed) in an outpatient psychiatry clinic "clinical" patient population versus a control outpatient general pediatric clinic "nonclinical" patient population. Survey results revealed an unanticipated inverse correlation regarding cosleeping with a higher frequency of cosleeping being reported by the "nonclinical" versus "clinical" patient populations.

Detail Summary Sheet

Prot No: 47H89* Status: Terminated

TITLE: Illicit Drug Use in Active Duty Motor Vehicle Accidents and Severe Trauma

Principal Investigator: CPT Lawrence A. Labbate, MC
Associate Investigators: CPT Douglas Jarvis, MC; CPT William Lynn, MC; CPT Andrew Guertler, MC; CPT William Hurley, MC; CPT Kraig Lerud, MC

Department/Section: Psychiatry

Key Words: drug;

Funding: FY 89: NA FY 90: NA Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: To study the prevalence of drug involvement among active duty personnel involved in traumatic accidents.

TECHNICAL APPROACH: Urine sample and blood sample will be collected from active duty troops involved in motor vehicle accidents multiple trauma. Urine will be analyzed for the presence of marijuana, cocaine, benzodiazepines, opiates, amphetamines. Blood alcohol level will be measured from the blood sample.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

*Exempt committee protocol.

This project was terminated due to PCS departure of principal investigator and three associate investigators. Unknown, but small, amount of data collected at initiation of project.

Detail Summary Sheet

Prot No: 17H90 Status: Ongoing

TITLE: A Psychophysiological Study of Chronic Post Traumatic Stress Disorder in Vietnam Veterans

Principal Investigator: MAJ Charles S. Milliken, MC
Associate Investigators:

Department/Section: Psychiatry

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: Validate the effectiveness of psychophysiological methods in diagnosing PTSD in combat veterans.

TECHNICAL APPROACH: Vietnam theatre male combat veterans who are presenting for mental health care will be assessed by extensive proven standards, methods, and pathophysiological methods. PTSD diagnoses arrived at by standard methods will act as the control against which comparisons will be made. The pathophysiologic method involves exposure to (1) vivid audiovisual scenes and (2) individually tailored narrative descriptions while monitored by standardized polygraph equipment.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period:

Patients recruited from the initially targeted VA ward at Tripler have been unsuitable because of the stringent requirement that all psychotropic and cardiovascular type medications be stopped. Renewed efforts to recruit from TAMC and Schofield Mental Health Clinic populations are being undertaken. Recruiting from the VA Clinic by the VA team continues.

Detail Summary Sheet

Prot No: 59H89 Status: Terminated

TITLE: Nutrition Assessment in Chronically Mentally Ill Patients

Principal Investigator: MAJ Rickie L. Pullen, MC
Associate Investigators:

Department/Section: Psychiatry

Key Words: nutrition assessment;

Funding: FY 89: NA FY 90: NA Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: To assess the prevalence of protein malnutrition among chronically mentally ill inpatients.

TECHNICAL APPROACH: All inpatients with chronic mental illness, excluding those with primary drug or alcohol problems will be asked to participate in a nutrition assessment. This will include interview and body measurements performed by the nutrition service and some chemistry studies. Chemistry studies will include: total lymphocyte count, serum albumin, serum transferrin. Data will be collected for six months or N=100.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Project has been terminated due to PCS departure of principal investigator.

Detail Summary Sheet

Prot No: 55H89 Status: Completed

TITLE: The Relationship Between Heavy Metal Music and Adolescent Turmoil

Principal Investigator: CPT Kevin J. Took, MC
Associate Investigators:

Department/Section: Psychiatry

Key Words: heavy metal music; adolescent functioning;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To investigate the association between heavy metal music and adolescent turmoil.
TECHNICAL APPROACH: Questionnaires will be given to adolescents, and to their parents. All of the adolescents will be between 12 and 18 years of age, and be patients at TAMC Child and Adolescent Psychiatry Clinic, the TAMC Adolescence Medicine Clinic, or the Adolescent Substance Abuse Counseling Service at Schofield Barracks. By utilizing these three different settings, patients with and without histories of adolescent turmoil will be included. A minimum of 50 subjects will be included in the study (25 HM and 25 NHM listeners). The adolescent questionnaire will focus on demographics, music preferences and listening habits, and current psychosocial functioning. The parental questionnaire will cover the adolescents' past and current psychosocial functioning, as well as questions about family demographics, parental music preferences and parental psychosocial functioning. There will be no identifying data on the questionnaires, only numbers to match the adolescent and parental questionnaires. The adolescents and parents will be separated while filling out the questionnaires and envelopes will be provided to seal the questionnaires after completion. Adolescents will be divided into HM and NHM listeners. To be considered a HM listener, an adolescent will have to list at least two HM bands/performers when asked to name his three favorite bands/performers. For the purposes of this study, a band/performer will be considered HM only if it has appeared in "Metal Edge" magazine and has releases with explicit lyrics about sex, violence (to include suicide and homicide), substance abuse, or Satanism.
PROGRESS: No. of Subjects Enrolled - To Date: 43 Reporting Period: 43
Forty three adolescents and their parents were enrolled in this survey study to look for a possible relationship between adolescents who listen to "Heavy Metal" rock music and increased incidence of adolescent turmoil (defined as poor psychosocial functioning as measured by age-appropriate adolescent adjustment and achievement indicators; i.e., school grades, peer relationships, relationships with parents, etc.). Results did indicate an increased incidence of poor psychosocial functioning (turmoil) in the "Heavy Metal" music listening group versus "non-Heavy Metal" listening control group. However, further research would be needed to establish if this association remains robust over time and if it is causal or if it is merely a frequent presenting symptom of other preexisting or comorbid adolescent or persistent preadolescent psychopathology.

Detail Summary Sheet

Prot No: 41H89 Status: Ongoing

TITLE: The Effects of a Multicomponent Smoking Cessation Program

Principal Investigator: Raymond A. Folen, Ph.D.
Associate Investigators: LTC Federico M.V. Tamayo, MS

Department/Section: Psychology

Key Words: smoking cessation;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To assess the effects of a weight control component in a smoking cessation program versus smoking cessation alone on recruitment of participants, attrition rates, cessation rates, and body weight changes.

TECHNICAL APPROACH: All individuals expressing an interest in the on-going smoking cessation program are contacted and, as a possible alternative, offered enrollment in one of the two experimental arms of the project. Subjects expressing an interest in the study are, after giving informed consent, placed in a) the six week behavioral-cognitive smoking cessation arm or b) the six week behavioral-cognitive and weight control component arm of the project. Participants not electing to participate in the study are provided with standard TAMC smoking cessation treatment. No adverse effects are to be reported, and no subjects have been withdrawn or dropped from the study.

PROGRESS: No. of Subjects Enrolled - To Date: 26 Reporting Period: 26

The study is terminated due to the fact that, at this point in time, the limited success in recruitment is far below the 100 subjects required for the study. Very few of the potential subjects were willing to enroll in the study given the standard alternative treatment at TAMC which includes a pharmacologic component (Nicorette).

Detail Summary Sheet

Prot No: 6H90 Status: Ongoing

TITLE: The Effects of Biofeedback-Assisted Self Regulation Training on Pilot Performance in Emergency Flying Conditions

Principal Investigator: Raymond A. Folen, Ph.D.
Associate Investigators:

Department/Section: Psychology

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: The purpose of this study is to determine the effects of biofeedback-assisted self-regulation (BASR) in a new application: pilot reactivity and performance during emergency flight situations. Specifically, the study addresses the effects of BASR on pilot performance and physiologic response to stressful emergency aircraft simulations.

TECHNICAL APPROACH: A pre-test/post-test control group design was used in this study. Subjects were volunteer active duty USCG HC-130 and HH-65 aircraft pilots. Subjects were randomly assigned to either the control or BASR group. Subjects in the BASR group received 12 BASR treatment sessions. Physiologic responses and pilot performance were measured during 'check rides' pre- and post- treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 17 Reporting Period:

Data collection has been completed. Initial analysis of the data indicates that BASR has a significant positive effect on pilot performance in emergency conditions. Additional statistical analyses are currently being run.

Detail Summary Sheet

Prot No: 31H88 Status: Ongoing

TITLE: Stimulant Drug Response in Attention Deficit Disordered Preschoolers

Principal Investigator: Dr. David S. Weiss, Ph.D.
Associate Investigators: Dr. Thomas E. Gallagher, M.D.

Department/Section: Psychology

Key Words: attention deficit disorder; Ritalin;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine the efficacy and side-effects of Ritalin (methylphenidate) and Dexedrine (dextroamphetamine) with preschool children (3-5 years of age) diagnosed as having an Attention Deficit Disorder.

TECHNICAL APPROACH: Children diagnosed with Attention Deficit Disorder, aged 3-5 years, will be given Ritalin, Dexedrine, and placebo in a counter-balanced, double-blind, crossover design (5 weeks in each condition). Ratings will be obtained form parents as well as direct tests of attention and impulsivity on the children, prior to entry in the study and in the last week of each condition. A side effects questionnaire will also be completed by the parents.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 2A

We now have two children of appropriate age and diagnosis who have just been enrolled in the study.

Detail Summary Sheet

Prot No: 32H83 Status: Ongoing

TITLE: Prospective Study of the Use of Urinary D-Lactate Levels in Evaluation of the Acute Abdomen

Principal Investigator: COL Peter J. Barcia, MC
Associate Investigators: CPT Vik Zadoo, MC

Department/Section: Surgery/General Surgery

Key Words: urinary D-lactate; acute abdomen;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine the usefulness of serum D-lactate levels in the evaluation of the acute abdomen.

TECHNICAL APPROACH: Patients evaluated for acute abdominal pain will have urinary D-lactate and creatinine specimens collected every 12 hours from the initial evaluation until four collections postoperatively or it is determined the patient does not have an acute abdomen. In addition, ten preoperatively to serve as controls.

PROGRESS: No. of Subjects Enrolled - To Date: 65 Reporting Period: 1

Ongoing; we had run into problems in the clinical laboratory since they were unable to run the specimens for us. We are in the process of hiring a lab tech (½ time paid by lab, ½ time paid by Dept. of Surgery) to continue and enlarge this study.

Detail Summary Sheet

Prot No: 25H89* Status: Terminated

TITLE: Urinary D-Lactate: A Specific Indicator of Intestinal Ischemia

Principal Investigator: COL Peter J. Barcia, MC
Associate Investigators:

Department/Section: Surgery/General Surgery Service

Key Words: urinary D-lactate;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: To demonstrate that elevated urinary D-lactate levels are a useful diagnostic indicator of intestinal ischemia.

TECHNICAL APPROACH: Urinary D-lactate values are available from 73 random patients admitted with abdominal pain, and from 8 control patients without abdominal pain. Specimens were obtained prior to any surgical intervention under previous protocols of the above Associate Investigator. (Some serial post-operative specimens were obtained as well, but are not used in this study). Urine was analyzed for D-lactate on a molar basis per unit of creatinine. No statistical analysis of this data has previously been done. Patients will be divided into 2 groups: those found to have ischemic intestinal conditions, and those with other conditions. D-lactate values of the 2 groups will be compared using X^2 analysis. If a significant difference is noted, the critical value of urinary D-lactate (outside of which there is the highest likelihood of disease) will be determine.

PROGRESS: No. of Subjects Enrolled - To Date: 73 Reporting Period: 73

*Exempt from CIC/HUC committee protocol.

This protocol was terminated; being continued in lab with another protocol attempting to develop a rat model and also clinically, we are attempting to continue drawing these levels in patients.

Detail Summary Sheet

Prot No: 34H89 Status: Terminated

TITLE: Water Sports Injury in Hawaii (Retrospective Study)

Principal Investigator: CPT Stephen S. Davis, MC
Associate Investigators: G. Harley Hartung, Ph.D.; Gary A. Okamoto, MD; Raymond M. Taniguchi, MD; Deborah A. Goebert, MS

Department/Section: Surgery/Orthopedic Service

Key Words: water sports injuries;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: In an effort to determine the extent to which major water sports injuries result in serious disability, a retrospective study of cases from 1985-1988 will be conducted. This information is needed in order to help in the development of and to call attention to planned preventive efforts within the state.

TECHNICAL APPROACH: Before attempting to prevent water sports injuries, more information is needed regarding the incidence of such injuries, geographical and activity specific data, and descriptive characteristics of persons likely to sustain serious injury. Medical records will be reviewed for all admitted cases of traumatic brain injury, spinal cord injury, drowning, near drowning, broken bones, internal injuries, and hyperbaric complications for the last four years at major hospitals across the state. Injuries which occurred between 1 January 1985 and 31 December 1988 will be reviewed. For those injuries resulting from water sports, data will be abstracted as to demographic characteristics of the patient, diagnosis, cause and location of the injury, resulting disability, length of hospital stay, therapies used in rehabilitation, and discharge status.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Project was terminated; Dr. Davis is a resident at Shriners Hospital now.

Detail Summary Sheet

Prot No: 24H88 Status: Terminated

TITLE: Water Sports Injuries in Hawaii

Principal Investigator: CPT Stephen S. Davis, MC
Associate Investigators: COL Michael J. Fay, MC; G. Harley Hartung, Ph.D.; MAJ Frederick Thaler, MC.

Department/Section: Surgery/Orthopedics Service

Key Words: water sports injuries;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: To establish a registry of information on water sports injuries in Hawaii.

TECHNICAL APPROACH: Data registry (cooperative state-wide program).

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No subjects were enrolled. Both investigators from Tripler were PCS'd and no arrangements made for follow up or continuation of this study.

Detail Summary Sheet

Prot No: 31H87 Status: Completed

TITLE: The Physiologic Response of Antidiuretic Hormone (ADH) and Human Atrial Natriuretic Factor (hANF) to Hypotonic Volume Expansion Secondary to Sorbitol Bladder Irrigation During Transurethral Prostatectomy (TURP)

Principal Investigator: CPT Paul M. Desmond, MC
Associate Investigators: MAJ L. Harrison Hassell, MC; LTC Gary Wikert, MC
John R. Claybaugh, Ph.D.

Department/Section: Surgery/Urology Service

Key Words: antidiuretic hormone; human atrial natriuretic factor;

Funding: FY 89: 323 FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To assess the effect of hypotonic volume expansion, secondary to absorbed sorbitol, during TURP on ADH, hANF, renin, aldosterone and fluid and electrolytes. Both uncomplicated TURP procedures and those associated with TUR syndrome (Transurethral Resection Syndrome) will be evaluated. To postulate the roles of ADH, hANF, renin and aldosterone in the pathophysiology of the TUR syndrome in order to : 1) predict which patients are susceptible 2) propose methods during TURP for the avoidance of the syndrome in susceptible patients and 3) provide greater understanding of the pathophysiology of the TUR syndrome so it can be appropriately treated when it occurs.

TECHNICAL APPROACH: Venipuncture; multiple blood samples, weights

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

In the process of writing a paper. We found that ADH increases during TUR syndrome and is contributory toward its development. Manuscript submitted - awaiting acceptance for publication.

Detail Summary Sheet

Prot No: 20H89 Status: Terminated

TITLE: Screening for Adenocarcinoma of the Prostate: A Prospective, Randomized Study with Multiple Endpoints

Principal Investigator: COL Martin L. Dresner, MC
Associate Investigators: COL William G. Kennon, MC; LTC Gary A. Wikert, MC

Department/Section: Surgery/Urology

Key Words: adenocarcinoma; prostate;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: To determine if transrectal ultrasound examination of the prostate improves sensitivity of screening evaluations and if early detection of carcinoma of the prostate reduces morbidity and mortality from the disease.

TECHNICAL APPROACH: Volunteers will be randomized to method of exam: rectal alone vs. rectal plus transrectal ultrasound. Groups will be compared as to diagnosis of CA of prostate time to metastatic disease, and time to death.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Study has been terminated.

Detail Summary Sheet

Prot No: 14H89 Status: Ongoing

TITLE: A Randomized Prospective Comparison of Operative Versus Non Operative Treatment of Third Degree Acromioclavicular Separation

Principal Investigator: CPT Rolf R. Drinhaus, MC
Associate Investigators: COL Michael J. Fay, MC

Department/Section: Surgery/Orthopedic Service

Key Words: acromioclavicular separation;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To gain further insight into shoulder function after operative versus nonoperative treatment of third degree Acromioclavicular separations; specifically by comparing the strength of the two shoulders in various motions. This should provide data to help the clinician better determine in which patients open repair should be performed.

TECHNICAL APPROACH: Patients with third degree acromioclavicular separations who agree to participate are randomized into operative and nonoperative groups. Operative treatment consists of a Weaver-Dunn acromioplasty with the addition of coracoclavicular suturing when possible. Nonoperative treatment currently consists of a sling or shoulder immobilizer until the discomfort subsides. Patients are evaluated subjectively with a questionnaire, objectively with shoulder strength testing and radiographically. There have been no operative infections, neurovascular complications, problems with screw breakage or other adverse effects to date.

PROGRESS: No. of Subjects Enrolled - To Date: 20 Reporting Period: 20

The principal investigator on this protocol is currently at Shriners Hospital. Per Dr. Drinhaus, the project is ongoing, data has been collected, evaluated and documented on 18 of the 20 patients enrolled in this study. No new patients have been enrolled.

Detail Summary Sheet

Prot No: 25H86 Status: Terminated

TITLE: The Quadriceps to Hamstring Ratio

Principal Investigator: COL Michael J. Fay, MC
Associate Investigators: CPT Charles R. Scoville, SP; SFC Richard W. Weeks; 1LT Leanne M. Pentland, SP; CPT Robbin Rowell, SP.

Department/Section: Surgery/Orthopedic Service

Key Words: quadriceps; hamstring ratio;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: The purpose of this study is to determine the normal values for concentric and eccentric quadriceps to hamstring strength ratios in an athletic population, with normal knees, between the ages of 17 and 35.

TECHNICAL APPROACH: This study will use infantrymen and assorted support troops from the 25th Infantry Division (Light). We expect that approximately 200 subjects will be tested. We will collect measurements including body type, height, weight, and thigh girths. The subjects will undergo a brief orientation on the purpose of the study and the equipment used. They will then be tested on the Kin-Com. The Kin-Com is a computer driven, hydraulic resisted device, allowing dynamic torsional forces to be recorded at set velocities throughout a pre-selected range of motion using both concentric and eccentric muscular contractions.

PROGRESS: No. of Subjects Enrolled - To Date: 8 Reporting Period: 8

This protocol has been terminated due to the following:

1) Lack of cooperation in obtaining subjects.

2) Principal investigator has moved and made no arrangements for continuation.

Detail Summary Sheet

Prot No: 46A89 Status: Ongoing

TITLE: Use of Fibrin Glue to Achieve Hemostasis in Solid Organ Injury

Principal Investigator: CPT Scott A. Fengler, MC
Associate Investigators:

Department/Section: Surgery/General Surgery Service

Key Words: fibrin glue; hemostasis;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To evaluate the efficacy and safety of the use of Fibrin glue (concentrated human fibrinogen and clotting factors) as a hemostatic agent in solid organ injury.

TECHNICAL APPROACH: An injury will be created of the spleen and fibrin glue will be injected intraparenchymally in an attempt to control bleeding.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Currently awaiting the arrival of a dual-lumen syringe for injection of fibrin glue. Pilot animals have not worked well due to attempted use of two single-lumen syringes. Also, we will try pilot pig liver and goat liver and spleen for better bleeding model.

Detail Summary Sheet

Prot No: 5H90 Status: Ongoing

TITLE: Analysis of Multiple Risk Factors and Their Effect on Troop Readiness

Principal Investigator: CPT Scott A. Fengler, MC
Associate Investigators:

Department/Section: General Surgery Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To evaluate the various risk factors (tobacco, alcohol, obesity, age) on troop readiness.

TECHNICAL APPROACH: Initial survey gathered for baseline data, then data was gathered for all clinic visits for approximately three months. The numbers of visits and the diagnoses are to be evaluated for possible significance of risk factors.

PROGRESS: No. of Subjects Enrolled - To Date: 1,700
Reporting Period: Through September, 1990

Data now being analyzed.

Detail Summary Sheet

Prot No: 7H90 Status: Completed

TITLE: Osteotomy of the Coracoid Process for Evaluation of the Distal Brachial Plexus

Principal Investigator: CPT Douglas S. Fugate, MC
Associate Investigators: CPT Ellen G. Shaver, MC; MAJ Kevin T. Foley, MC, COL Michael J. Fay, MC

Department/Section: Department of Surgery/Orthopedic Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: To study and determine access to the distal brachial plexus and axillary nerve from exposure utilizing an osteotomy of the coracoid process.

TECHNICAL APPROACH: We propose to examine the distal brachial plexus (at or beyond the level of the cords) of both shoulders of ten (10) fresh (unembalmed) cadaver specimens. Standard shoulder deltopectoral groove incisions will be made. Once the coracoid process is identified and coracoacromial and coracoclavicular ligaments resected, then an osteotomy of the coracoid process will be completed. The coracoid process and attached conjoined tendon will be reflected inferiorly to expose the distal brachial plexus. Once the plexus is exposed, mapping of the corresponding lengths of each segment both proximally and distally will be done. We will also incise the insertion of the pectoralis minor for comparison since this is also utilized as an approach to the brachial plexus.

We expect to demonstrate that excellent exposure of the distal brachial plexus can be obtained through this less extensile dissection, and that through this technique, surgeons will be provided a more feasible approach for treating disorders of the brachial plexus.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Per Dr. Fugate of Ft. Leonardwood, MO, this paper has been submitted for publication in the Journal of Bone and Joint Surgery, Inc. and he is still waiting to hear when it will be published.

Detail Summary Sheet

Prot No: 40A87 Status: Ongoing

TITLE: Emergent Initiation of Cardiopulmonary Bypass in a Swine Model

Principal Investigator: CW3 David L. Hahn
Associate Investigators: COL Arthur W. Larson, MC; SFC Sam Morgan

Department/Section: Surgery/Thoracic Surgery Svc

Key Words: emergent cardiopulmonary bypass;

Funding: FY 89: $1,441 FY 90: $5,062 Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To introduce and familiarize personnel with the initiation of emergent cardiopulmonary bypass (ECPB) procedure using the swine model.

TECHNICAL APPROACH: Identify problems associated cardiopulmonary bypass e.g., aspiration pneumonia, cardiac damage, and implement appropriate actions, i.e., stabilization, cannulation, heparinization and performance of cardiopulmonary bypass.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

To date, ten pigs have been done. One or two pigs are scheduled for each month period. During this time a senior general surgery resident is on cardiothoracic surgery rotation. During the rotation they learn surgical techniques for heart surgery and how to assist with emergent bypass. Request the research project be continued.

Detail Summary Sheet

Prot No: 15T85	Status: Ongoing
TITLE: Animal Models for Advanced Trauma-Life Support Provider and Instructor Courses	
Principal Investigator: LTC Eric A. Johnson, MC Associate Investigators: COL Donald W.S. Yim, MC;	
Department/Section: Surgery/General Surgery	
Key Words: advanced trauma life support;	
Funding: FY 89: $1,630 FY 90:$4,663 Gifts: None	Periodic Review Date: Sep 90 Decision: Continue

OBJECTIVE: To fulfill the requirement of ATLS Provider and Instructor courses, i.e., to teach physicians a standardized approach to trauma care in the early hours of trauma patient assessment and to teach life-saving skills using animal models.

TECHNICAL APPROACH: Goats or pigs are deeply anesthetized with sodium pentobarbital and prepared for surgery. Participants then perform cricothyroidotomy, peritoneal lavage, chest tube placement, pericardiocentesis, and venous cutdown procedures under the close supervision of certified instructors. Animals are euthanized at the end of the surgery laboratory.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Adverse effects and subjects dropped/withdrawn: None

Sixteen students successfully completed the ATLS instructor course from 27 - 29 March 1990 (utilized four goats). Have scheduled a 16-student (4 goat) ATLS provider course for 4 - 5 December 1990.

Detail Summary Sheet

Prot No: 38A89 Status: Ongoing

TITLE: "Use of Auto Suture Co. (U.S. Surgical Corp.) Surgical Stapling Instruments in the Training of Residents on Pigs"

Principal Investigator: MAJ Gregory J. Kechejian, MC
Associate Investigators: General Surgery Residents

Department/Section: General Surgery

Key Words: Stapling

Funding: FY 89: FY 90: $6,597 Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To teach proper stapling techniques and precautions to residents using the AUTO Suture Co. TA, GIA, EEA instrumentation on the intestines and stomach. End to end, side to side colon and small intestinal anastomoses will be performed using all instruments. Anastomoses between portions of the small intestine and from small intestine to stomach and colon will be done. Anastomoses between the colon and rectum will be done. Transection of the stomach, colon and small intestine will be performed.

TECHNICAL APPROACH: Using an abdominal approach, portions of small bowel, large bowel and stomach will be mobilized enabling the surgeon to perform bowel to bowel and bowel to stomach anastomoses. Closure of the animal will include fascia staples and skin staples.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Ongoing teaching labs to date approximately 48 resident sessions have been held.

Detail Summary Sheet

Prot No: 42A89 Status: Ongoing

TITLE: Experimental Techniques of Liver Surgery

Principal Investigator: CPT Thomas Knuth, MC
Associate Investigators: LTC Lawrence C. Runke, MC

Department/Section: Surgery/General Surgery Service

Key Words: liver surgery; re-anastomose;

Funding: FY 89: $855 FY 90: $5,081 Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: (1) To resect a portion of the liver and re-anastomose that portion in its same location or in another location and/or resect and re-implant the entire liver. (2) To maintain systemic and portal venous blood circulation via temporary catheterization while the liver is removed from the animal's circulation. (3) To re-implant the liver back into the animal resulting in a fully recovered live animal upon completion of the procedure. (4) To assess the liver damage in the post operation period by serial chemical analysis.

TECHNICAL APPROACH: We will develop techniques to rapidly mobilize and remove the entire liver from a pig. We will then establish vena caval and portal blood flow to the heart while the liver is out of the body cavity. Techniques will be developed to rapidly resect and/or repair damaged liver tissue and then reimplant the liver into the animal. Techniques will be used and developed to maintain the viability of the liver while out of the body cavity including but not limited to liver hypothermia and perfusion of the liver with nutrient solutions.

PROGRESS: As of 30 Sept 90, ten pigs have been operated on. The technical aspects of bench surgery on the liver have just about been worked out. A remaining problem is the suprahepatic vena caval anastomosis, which, because of limited space and transection of an already short segment of vein, is an extremely difficult anastomosis unless the diaphragm is incised, and this adds morbidity to the procedure. We may need to try a prosthetic interposition graft. Otherwise, we are ready to attempt to recover an animal.

For our last 2 - 3 procedures, we have had tremendous support from the anesthesia department, which provided a nurse anesthetist student, from the thoracic surgery department which provided a perfusionist, and from the department of clinical investigation by way of a scrub assistant. Each member of this team provided invaluable assistance in keeping our animals alive and will be needed again if this surgery is to be successful. Additionally, we may need blood bank support or we may need to collect and store pig blood ourselves for our next case.

I spent a week in Portland, Oregon, working with Dr. C.W. Pinson and I had the opportunity to assist on three human liver transplants as well as see his pig lab and learn his techniques, so I think we can now be successful here.

Detail Summary Sheet

Prot No: 60H89 Status: Terminated

TITLE: Study of Unasyn vs. Cefoxitin for Perioperative Treatment in Abdominal Operations

Principal Investigator: CPT Thomas E. Knuth, MC
Associate Investigators:

Department/Section: Surgery/General Surgery Service

Key Words: unasyn; cefoxitin;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: This protocol proposes to study Unasyn as a perioperative and/or therapeutic agent in abdominal surgeries as compared to Cefoxitin.

TECHNICAL APPROACH: To use Unasyn or Cefoxitin in a prospective double blinded fashion for the perioperative treatment of a variety of general surgical conditions. Clean contaminated cases will receive preoperative antibiotics only while contaminated and dirty cases will receive a therapeutic course as needed.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Approximately 20 - 30 subjects were enrolled in the study prior to my departure and during my initial absence for an "away" clinical rotation. Due to lack of interest in the department, enrollment fizzled and no subjects have been enrolled for the past 5 - 6 month period. The project is terminated.

Detail Summary Sheet

Prot No: 42H88 Status: Ongoing

TITLE: Treatment of Lipomatosis with Non-Steroid Anti-inflammatory (NSAI) drugs and Tamoxifen

Principal Investigator: COL Y-T. Margaret Lee, MC
Associate Investigators:

Department/Section: Surgery/General Surgery Service

Key Words: tamoxifen; lipomatosis;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if multiple lipomatosis will respond to Indomethacin, and/or Sulindac and/or Tamoxifen. (There are reports in the literature that reported that colonic polyposis and desmoid tumors did shrink with the treatment of these 3 drugs, either singularly, or in various combinations).

TECHNICAL APPROACH: Patient will be given Indomethacin first for two months. If there is evidence of shrinkage, the drug will be continued. If there is no response, the drug will be stopped for a month. Then Sulindac will be tried. Tamoxifen will be the third drug to be used. All 3 drugs are included in the TAMC Formulary and conventional doses will be used.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Only one patient has been enrolled in August of 1988. He received Indomethacin for two months and decided not to continue. There was no therapeutic effect noted, also no side effect noted. I am looking for another suitable patient to treat.

Detail Summary Sheet

Prot No: 19H87 Status Ongoing

TITLE: Peritonsillar Abscess: Treatment with Needle Aspiration and Oral Antibiotics vs. Incision and Drainage and IV Antibiotics

Principal Investigator: CPT Kevin C. Lunde, MC
Associate Investigators: All otolaryngology staff and residents

Department/Section: Surgery/Otolaryngology Service

Key Words: peritonsillar abscess;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To establish an effective treatment regimen for peritonsillar abscess which can be utilized by non-otolaryngologists and paraprofessional personnel in a military field setting.

TECHNICAL APPROACH: The peritonsillar area is aspirated three times with a syringe and 18 gauge needle, if pus is found they are enrolled (offered enrollment) in the study.

PROGRESS: No. of Subjects Enrolled - To Date: 18 Reporting Period: 18

With all the staff in agreement we have been able to enroll more subjects into the study. More time will be needed to reach our goal.

Detail Summary Sheet

Prot No: 21H90 Status: Ongoing

TITLE: DNA Ploidy of Hypoechoic Prostate Carcinomas: Correlation of Transrectal Ultrasonography and Flow Cytometry

Principal Investigator: CPT Allen F. Morey, MC
Associate Investigators:

Department/Section: Surgery/Urology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: 1) To determine if hypoechoic prostate carcinomas differ in DNA ploidy from tumors having hyperechoic, isoechoic, or mixed sonographic patterns.
2) To correlate DNA ploidy with size, and Gleason tumor grading scores of prostate carcinomas
3) To determine if prostate cancers detected on transrectal ultrasound (TRUS) correlate with the presence of a palpable nodule.

TECHNICAL APPROACH: Single extra ultrasound-directed biopsy cores will be obtained from areas of hypoechoic, mixed, and/or hyperechoic appearance; size of lesion and presence of capsular distorsion will be noted. If no visible abnormalities are noted, a minimum of one extra biopsy will be obtained from each side of the isoechoic gland, thus comprising a control group.

The presence or absence of a palpable nodule will be noted with each specimen. The result will be a total of two extra samples per patient.

PROGRESS: No. of Subjects Enrolled - To Date: 50 Reporting Period:

Fifty men have been enrolled in this study to September 1990 (6 of these 50 have cancer).

The technical approach to this protocol will remain the same -- sending an extra specimen for DNA ploidy/correlation with histopathologic disease status.

Plan to add companion study: same procedure as above prior to TURP. Patient will already be anesthetized and on IV antibiotics so no additional discomfort or risk of infection. It is the same protocol, just adding surgical BPH as an indication for prostate biopsy.

Detail Summary Sheet

Prot No: 62H88 Status: Completed

TITLE: The Role of Ultrasonography in the Diagnosis of Acute Appendicitis: A Prospective Study

Principal Investigator: CPT Linda Murray, MC
Associate Investigators: COL Peter Barcia, MC; CPT Gregory Logsdon, MC; MAJ Thomas Leutkehans, MC

Department/Section: Surgery/General Surgery Service

Key Words: ultrasonography; acute appendicitis;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: To demonstrate that abdominal ultrasound is a useful diagnostic adjunct in cases of acute appendicitis.

TECHNICAL APPROACH: Upon admission to the General Surgery service to rule out appendicitis, real-time ultrasonography of the abdomen is performed in the radiology suite by Dr. Logsdon or Dr. Leutkehans. Results are unavailable to the admitting physician for 12 hours after performance of the exam by which time, clinical decisions have been made and therapy initiated.

PROGRESS: No. of Subjects Enrolled - To Date: 100 Reporting Period: 100

We performed high-resolution, real-time ultrasonography on 100 patients admitted to rule out appendicitis in a prospective double blind manner. Surgical therapy was initiated solely on clinical grounds and diagnostic accuracy compared to that of ultrasonography. Forty of these patients had appendicitis and in every instance, the decision to operate was appropriately made for a sensitivity of 100%.

Ultrasonography had a sensitivity of 70%. The specificity of the sonographic exam at 85% was slightly better than that of the surgeon. Accuracy of ultrasonography proved only 79% in the hands of our radiologists, whereas that of diagnosis by the surgical staff was 87%. A negative appendectomy rate of 24.5% was experienced.

It is our conclusion therefore, that the diagnosis of appendicitis remains a clinical one based on history, physical exam and supporting laboratory data, and for which no other accurate diagnostic modality exists.

Detail Summary Sheet

Prot No: 56H88 Status: Ongoing

TITLE: The Use of Absorbable (Poly-p-dioxanone) Pins Versus Kirschner Wires for Internal Fixation of Chevron Osteotomies for Hallus Valgus

Principal Investigator: CPT Craig M. Ono, MC
Associate Investigators: MAJ Barney Yanklowitz, MS

Department/Section: Surgery/Orthopedic Service

Key Words: kirschner wires; chevron osteotomies;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: Study will describe the utility of the poly-p-dioxanone absorbable pin versus the Kirschner wire in the internal fixation of chevron osteotomies for the correction of the hallux valgus deformity.

TECHNICAL APPROACH: The standard (Austin) Chevron bunionectomy/osteotomy will be completed following standard preoperative, intraoperative, and postoperative criteria. The standard Kirschner wire fixation technique requires further minor surgery for its removal. The orthosorb pin fixation technique does not. No less than 27 cases of Orthosorb fixation Chevron procedures will be compared to Kirschner wire fixated cases by objection and subjective parameters: range of motion, foot x-rays, patient satisfaction, complications, clinical presentation.

PROGRESS: No. of Subjects Enrolled - To Date: 9
Reporting Period: November 1989 - October 1990

No adverse affects. Four (4) dropped due to P.C.S. orders.

Presently, the Operating Room has enough for nine more cases. Due to the cost of this item, only nine Orthosorb pins will be ordered per quarter. It is expected to take 18 to 24 months to complete this study.

Detail Summary Sheet

Prot No: 50H85 Status: Ongoing

TITLE: Arthroscopic Evaluation of Acute Primary Shoulder Dislocations

Principal Investigator: CPT J. David Pitcher, Jr., MC
Associate Investigator: COL Michael J. Fay, MC

Department/Section: Surgery/Orthopedics

Key Words: shoulder dislocation; arthroscopy;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To evaluate arthroscopically the lesions associated with shoulder dislocations and correlate these lesions with prognostic indicators relative to recurrent dislocations.

TECHNICAL APPROACH: Patient referral requests will be sent to all outlying clinics requesting referral of all patients with initial shoulder dislocations documented by radiographs. Patients entered into the study will be admitted to TAMC Orthopedic Service and placed on the surgery schedule. Arthroscopy will be performed as soon as possible after the injury. Intra-articular pathology will be documented on operative findings data sheets and photographs of pathology will also be maintained in the data file for each patient. Postoperatively, patients will be placed in shoulder immobilizers for three weeks, followed by physical therapy with range of motion and shoulder bridle strengthening program for four weeks. Patients will then be progressed to full duty over a four-week period, and will be followed monthly in Sports Medicine Clinic for six months to one year, documenting clinical progress. Subsequent clinical progress and recurrent dislocation will be correlated with initial pathology documented by arthroscopy.

PROGRESS: No. of Subjects Enrolled - To Date: 50 Reporting Period: 50

We have sent out multiple questionnaires to all participants and have received fifteen responses. We are having difficulty contacting the participants (total number of 50). Another wave of questionnaires has been planned to be mailed out.

Detail Summary Sheet

Prot No: 14T85 Status: Ongoing

TITLE: Microvascular Lab-Psychomotor Skills

Principal Investigator: LTC Elizabeth C. Quinlan, MC
Associate Investigators: CPT Steven S. Davis, MC; CPT Rolf R. Drinhaus, MC; CPT Richard M. Cirillo, MC

Department/Section: Surgery/Orthopedic Service

Key Words: training; psychomotor skills;

Funding: FY 89: $1,088 FY 90: $4,596 Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To train residents in the repair of arteries and veins approximately 1 mm in diameter.

TECHNICAL APPROACH: Rats are anesthetized with sodium pentobarbital and one femoral artery and/or vein is transected and then reanastomosed. The wound is observed daily for any complications.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

The project is continuing. The neurosurgery intern has completed her training. One orthopaedic resident completed the "in vitro" suturing practice but was not able to get into the lab because the rats all had to be sacrificed due to a contagious illness. The rat colony has now been built up again and training will resume. Dr. Milnor is presently at a microsurgical refresher course and should be added to the protocol as staff.

Detail Summary Sheet

Prot No: 15A87 Status: Ongoing

TITLE: Menisci Energy-Absorbing Characteristics of Pig Hind Knee with Both Sattic and Dynamic Loads

Principal Investigator: CPT Kenneth Reesor, MC
Associate Investigators: COL Kent Reinker, MC; MAJ John Uribe, MC
Wayne Ichimura, Biomedical Engineer

Department/Section: Surgery/Orthopedic Service

Key Words: meniscal injuries;

Funding: FY 89: $4,212 FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To establish the energy-absorbing characteristics of the pig knee and to determine if these characteristics are dependent on the percentage of meniscal intact.

TECHNICAL APPROACH: Instrumentation to apply impact loading to isolated pig knees (slaughterhouse donation) will be developed and measurements made of 1) transmitted pressures 2) compression displacements and 3) circumferential elongation or expansion of exercise.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Transfer to another resident.

Detail Summary Sheet

Prot No: 20H90 Status: Ongoing

TITLE: Radiologic Evaluation of Cervical Spine Trauma; A Selective Approach

Principal Investigator: CPT Bradley Roth, MC
Associate Investigators:

Department/Section: General Surgery Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To answer the following questions: 1. Can a selective approach to obtaining cervical spine radiographs be utilized for trauma patients without overlooking significant cervical spine injuries? 2. Can oblique radiographs of the cervical spine be eliminated from a "standard trauma cervical spine x-ray series" without sacrificing diagnostic accuracy?

TECHNICAL APPROACH: All patients that are seen in TAMC's ER for a decelerating type injury or trauma to the neck will be entered into the study. All patients will have a documented physical exam and five view cervical spine radiograph evaluation completed. If no injury was noted on their initial evaluation, they will be seen in thirty days to be evaluated for possible occult cervical injury.

PROGRESS: No. of Subjects Enrolled - To Date: 17 Reporting Period: 17

Seventeen patients are enrolled in this study to date. This study is presently on hold until questions regarding consent are evaluated.

Detail Summary Sheet

Prot No: 28H89 Status: Ongoing

TITLE: Clinical Evaluation of a Percutaneous Pneumothorax Catheter Vs. Standard Tube Thoracostomy for the Treatment of Pneumothorax

Principal Investigator: CPT Bradley J Roth, MC
Associate Investigators: LTC Greg A. Bowman, MC

Department/Section: Surgery/Cardiothoracic Surgery Service

Key Words: pneumothorax catheter

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: Pneumothorax is a common disease that has routinely been treated with a tube thoracostomy. Recently many studies have shown that this disease may be treated with a much smaller pneumothorax catheter. This study will compare the two types of treatment for non-complicated pneumothorax in an attempt to support the hypothesis that the use of the pneumothorax catheter is less effective than tube thoracostomy.

TECHNICAL APPROACH: A chest tube on pneumothorax catheter is placed into the chest for the treatment of pneumothorax. The patient remains in the Protocol for 3 days. If the pneumothoras has not resolved than other treatment modalities are used.

PROGRESS: No. of Subjects Enrolled - To Date: 17 Reporting Period: 17

Seventeen patients enrolled to date. Study progressing well.

Detail Summary Sheet

Prot No: 52H88 Status: Completed

TITLE: Biomechanical Aspects of Olecranization of the Patella

Principal Investigator: CPT James L. Rungee, MC
Associate Investigators: COL Michael J. Fay, MC;
Wayne Ichimura, Biomedical Engineer

Department/Section: Surgery/Orthopedic Service

Key Words: patella; olecranization;

Funding: FY 89: $1,468 FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: a) To study and determine whether olecranization of the patella actually functions to relieve tension across repairs and reconstructions of the Posterior Cruciate Ligament of the knee, and b) If tension is indeed lessened, to determine the ideal position and method of pin placement that affords limited post-operative knee motion while still protecting the Posterior Cruciate Ligament repair.

TECHNICAL APPROACH: Biomechanical measurements of surgical procedure.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

The portion of this protocol requiring the use of whole cadaver specimens has been terminated. The data obtained to date has been analyzed and determined to be of sufficient nature to allow conclusions to be made. We will continue to utilize above-the-knee amputation specimens as they become available until the final manuscript is prepared and submitted for publication. All modified autopsy request regarding this protocol have been removed from unit death packages.

The results of this protocol are being prepared and will be reported under the title "Biomechanical Implications of Olecranization of the Patella."

Detail Summary Sheet

Prot No: 49H88 Status: Completed

TITLE: The Changing Spacial Relationship of the Patella and Tibia in Normal Knee Motion

Principal Investigator: CPT James L. Rungee, MC
Associate Investigators: 2LT Thomas M. DeBerardino, MS;
COL Michael J. Fay, MC

Department/Section: Surgery/Orthopedic Service

Key Words: normal knee motion;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To radiographically determine and document the motion of the patella in space relative to the tibia during normal knee motion.

TECHNICAL APPROACH: Ten (10) volunteers will be picked at random for radiographic evaluation of both knees. To qualify for the study, the participants must have asymptomatic knees, free of instability or other pathologic process as documented by clinical and routine radiographic examination. Lateral radiographs of each knee will be obtained at predetermined degrees of flexion (0, 30, 60, and 90 degrees) as confirmed by gniometric measurement. Using the tibial profile as reference, the spacial motion of the patella will be plotted, measuring specifically:
a) the antero-posterior excursion of the patella, and
b) the changing longitudinal tilt of the patella.
Diagramatic tracings as well as graphical plottings will be utilized to establish the basic characteristic and mean spacial changes of the patello-tibial relationship.

PROGRESS: No. of Subjects Enrolled - To Date: 10 Reporting Period: 10

All x-rays have been taken. No ill effects have been reported. Measurements have been performed and the data is currently being analyzed. A large portion of the paper has already been written. Planned complet.. date is February 1990.

The results of this protocol are being prepared and will be reported under the title "Biomechanical Implications of Olecranization of th_ Patella."

Detail Summary Sheet

Prot No: 14A90 Status: Ongoing

TITLE: New Zealand White Rabbits as a Model for Induced Bipolaris Sinusitis

Principal Investigator: CPT Christopher K. Sinha, MC
Associate Investigators: MAJ L. Zieske, MC; CPT M. Sheridan, MC; MAJ R. Kopke, MC

Department/Section: Department of Surgery/General Surgery Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: 1) To determine if the sinuses of the New Zealand White Rabbit will develop a fungal sinusitis with a Bipolaris species. 2) To determine the quantity of inoculant per area of sinus mucosa required for induction of fungal sinusitis.

TECHNICAL APPROACH: Animals will be separated into four groups. Group #1 will consist of control rabbits that receive no inoculant of Bipolaris hawaiiensis. This group, however, does undergo sham operation. Groups #2, #3. and #4 receive 0.5, 1.0, and 3.0 McFarland units of inoculant respectively. Control animals will be housed in a separate room. Immediately post inoculation, sinus x-rays are obtained for baseline study. On a weekly basis, sinus x-rays are obtained.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start. No progress to report.

Detail Summary Sheet

Prot No: 45A89 Status: Ongoing

TITLE: Nonanatomic vs Anatomic Liver Resection in Pigs

Principal Investigator: CPT Martin Tieva, MC
Associate Investigators: COL Peter Barcia, MC

Department/Section: Surgery/General Surgery Service

Key Words: non-anatomic liver resection

Funding: FY 89: NA FY 90: NA Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To demonstrate the speed, efficacy and safety of non-anatomic liver resection.

TECHNICAL APPROACH: Four pigs will have an anatomic resection and 4 pigs will have a non-anatomic resection. The outcome of the two groups will be compared as well as operative time and blood loss. At the end of the experiment, the animals will be euthanized and a cast made of their vasculature.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

This protocol has been placed on hold - due to lack of time, no work has been done on this study.

Detail Summary Sheet

Prot No: 26H90 Status: Ongoing

TITLE: Laparoscopic Appendectomy

Principal Investigator: CPT Frederick T. Work, Jr, MC
Associate Investigators: LTC Lawrence C. Runke, MC;
LTC Gerard S. Letterie, MC

Department/Section: Surgery/General Surgery

Key Words: laparoscopic appendectomy

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if laparoscopy is a tool which, in skilled hands, may be quickly, safely and effectively used to expedite early diagnosis of appendicitis and its surgical treatment.

TECHNICAL APPROACH: Patients over the age of 18 with abdominal pain suspected of having appendicitis will be offered laparoscopic appendectomy with the exception of those who have undergone previous abdominal surgeries in the lower quadrants. Procedures will be performed under general anesthesia using a standard technique for introduction of the instrument into the peritoneal cavity. All non-participants in the study will be used as the control group in this prospective study.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: 28H88 Status: Ongoing

TITLE: Treatment Assessment of Multiple Plantar Warts with Acyclovir

Principal Investigator: MAJ Barney A. Yanklowitz, MS;
Associate Investigators:

Department/Section: Surgery/Orthopedic Service

Key Words: plantar warts; acyclovir;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To discover whether or not an occlusive foot dressing improves the reported results (25%, 38%, 39%) of topical 5% Acyclovir for the treatment of multiple plantar warts after 8 and then 12 weeks.

TECHNICAL APPROACH: A clinical investigation including 68 patients ages 2 to 70 (unless pregnant or nursing mother) with a clinical diagnosis of multiple plantar warts (6 or more) or a large surface area (greater than 2.54 cm. diameter) mosaic plantar warts will be treated.

PROGRESS: No. of Subjects Enrolled - To Date: 14 Reporting Period: 6

Project began on 6 September 1988 after a review of statistical analysis and patient selection protocol. Patient selection/participation will be low and completion of this project will take 48 months because I only treat one or two patients/month with this severe of wart infection. No patients withdrawn/dropped. No publications or presentations at this time.

Detail Summary Sheet

Prot No: 37H88 Status: Ongoing

TITLE: Sonography of Morton's Neuromas

Principal Investigator: MAJ Barney A. Yanklowitz, MS
Associate Investigators:

Department/Section: Surgery/Orthopedic Service

Key Words: Morton's neuromas;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To evaluate the size of the third webspace plantar nerve on sonography as a positive predictive indicator of biopsy confirmed Morton's neuromas.

TECHNICAL APPROACH: Aggressive conservative therapy for Morton's neuroma includes: examination of duty and recreational footgear; limitation or cessation of hyperextension (of MTPJ) causing activities for six weeks; the use of pedal orthoses (insoles, metatarsal pads) for six weeks; NSAID for 12 weeks; plantar intermetatarsal nerve blocks (local anesthetic and corticosteroid). After failure of aggressive conservative therapy or in the presence of a palpable mass, elective sonography of the affected webspace will be requested by a member of the Orthopedic Service. This routine sonography will be scheduled by appointment and completed by personnel assigned to the Ultrasound Section, Department of Radiology. The resultant hard copy images will be used by the attending Orthopedic staff for operative planning and patient education. Photographs of sonographs and neuromas (in situ or biopsied specimens) will be completed for no more than 48 patients. Neuromas will be confirmed by standard biopsy techniques.

PROGRESS: No. of Subjects Enrolled - To Date: 12 Reporting Period: 4

Study approved on 6 September 1988. This study will take at least 18 months. No adverse effects. No patients dropped/withdrawn. No publications or presentations at this time.

Detail Summary Sheet

Prot No: 22A89 Status: Ongoing

TITLE: Altered Consciousness Induced by Overdrainage of Cerebrospinal Fluid

Principal Investigator: COL Donald W. S. Yim, MC
Associate Investigators: COL Bernard Robinson, MC, USAR;
John R. Claybaugh, Ph.D.; MAJ Jon Graham, MC;
MAJ Kevin Foley, MC; MAJ James R. Doty, MC
Dr. Robert Jones, MD (Kaiser Medical Center)

Department/Section: Surgery/Otolaryngology Service

Key Words: cerebrospinal fluid;

Funding: FY 89: $303 FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To characterize altered consciousness induced by overdrainage of cerebrospinal fluid.

TECHNICAL APPROACH: To create an animal model in which coma can be induced by overdrainage of cerebrospinal fluid. Additionally, we hope to be able to demonstrate complete reversal of coma by replacing the volume of CSF removed. Various parameters of vital functions are to be monitored during the investigation. These include evoked responses (auditory, somatosensory, brainstem), blood pressure, electrocardiogram, and pulse rate. Intracranial pressure will also be measured. Cerebral blood flow monitoring is ultimately desired but will not be pursued until a suitable experimental model is confirmed. We hope to characterize any changes in these parameters induced by the test manuever (CSF Drainage). The test animal will require a craniectomy and insertion of a reservoir to be used for the actual access to the intrathecal compartment chosen form removal of CSF.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

No animals have been done in the past year.

Detail Summary Sheet

Prot No: 24A90 Status: Ongoing

TITLE: D-Lactate as a Serum Marker for Intestinal Ischemia in a Rat Model

Principal Investigator: CPT Vik Zadoo, MC
Associate Investigators: CPT David Watts, MC; COL Peter Barcia, MC
CPT Carol Eisenhauer, VC

Department/Section: Department of Surgery/General Surgery Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To identify a serum marker of intestinal ischemia before the onset of frank infarction.

TECHNICAL APPROACH: Two groups of rats will be used in the study. Group 1, the control group will be subjected to sham laparotomy, handling of the bowel and closure of the abdomen. Group 2 rats will all undergo laparotomy with ligation of the superior mesenteric artery at its origin.

The experiment will also include an additional 8 rats for a pilot study to investigate the potential problems in experimental procedures (i.e., timing, difficulty in obtaining blood, and response of d-lactate).

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start. No progress to report.

Detail Summary Sheet

Prot No: 33H90	Status: Ongoing
TITLE: D-lactate as a Serum Marker for Intestinal Ischemia in a Human Model	
Principal Investigator: CPT Vik Zadoo, MC Associate Investigators: COL Peter Barcia, MC; COL Robert Hill, MC	
Department/Section: Surgery/General Surgery	
Key Words: D-lactate; intestinal ischemia	
Funding: FY 89: FY 90: Gifts: None	Periodic Review Date: Sep 90 Decision: Continue

OBJECTIVE: To identify a serum marker of intestinal ischemia before the onset of frank infarction.

TECHNICAL APPROACH: Patients admitted to the TAMC General Surgery Service for an acute surgical abdomen will be enrolled in this study. They will have a serum and urine D-lactate level performed. Other data (e.g. admitting diagnosis, white blood cell count, blood pressure upon admission) will be correlated with the admitting d-lactate level.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start. No progress to report.

Detail Summary Sheet

Prot No: 7H88 Status: Ongoing

TITLE: Urine Detectability in Patients and Physicians of Intranasal 4% Topical Cocaine During Clinical Utilization

Principal Investigator: MAJ Larry A. Zieske, MC
Associate Investigators: MAJ Charles A. Moore, MS;
CPT Eileen M. Mahoney, MC; CPT Kevin C. Lunde, MC;
CPT Mark F. Sheridan, MC; CPT Christopher Sinha, MC
CPT Sharon M. Tomaski, MC; CPT Philip Wiley, MC;
CPT Christopher Himmelhieber, MC

Department/Section: Surgery/Otolaryngology Service

Key Words: topical cocaine;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine the detectability of intranasally applied 4% topical cocaine in patients and physicians, applying this in their routine clinical practice. A dose versus time post-exposure graph is to be sought. To determine the protectability of surgical gloves to the applying physician. To determine cutaneous absorption of cocaine by urine drug screening.

TECHNICAL APPROACH: To obtain base lines on each physician and patient. To sample patients urine post controlled and documented exposure to cocaine by ENT physicians. The sampling will be: First 6-8 hours post-op and then on a daily basis for 3 days (beyond the normally expected point of negative detection) after any cocaine exposure. Quantification of urine metabolite level will be done as much as possible. Physician samples will also be obtained after use of cocaine with and without latex glove use to check for glove protection and cutaneous absorption. Approximately 24 exposures will be monitored (24 patient and 24 surgeons). The analysis will be by IRA and mass spectrometry. Documenting of all medications will be done (over the counter and prescribed). Chain of custody will be maintained.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Project to start when time available.

Detail Summary Sheet

Prot No: POG 8104(83) Status: Completed

TITLE: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: neuroblastoma;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: VM-26 Decision: Completed

OBJECTIVE: Attempts to reduce later complications by separating by age and stage those patients that require surgery only, surgery and chemotherapy, surgery, chemotherapy, and radiation therapy, etc.

TECHNICAL APPROACH: Pediatric patients and adolescent patients under the age of 18 with neuroblastoma are eligible for enrollment in this study. Treatment will be as outlined in the study protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 5 Reporting Period: 0

There were 62 eligible patients registered as of November of 1989, 33 in the XRT treatment group and 29 in the no XRT group. A complete response was seen in 76% of those children receiving XRT as compared to 46% in the group that did not receive XRT. Event free survival at 5 years from diagnosis for group C patients is 29% for the no XRT group and 57% for the XRT group.

Detail Summary Sheet

Prot No: POG 8158(83) Status: Ongoing

TITLE: NWTS Long Term Follow-up Study

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: Wilms' tumor;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To examine the late consequences of successful treatment given for Wilms' tumor.

TECHNICAL APPROACH: Pediatric patients and adolescent patients under 18 years of age with Wilms' tumor will be eligible. Treatment will be as outlined in the study protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients have been entered into this protocol as yet. This is a non therapeutic study designed to gather epidemiologic and late effects data on long term (>5yrs) survivors of Wilm's tumor. No Tripler patients have been registered to date. Nationally 181 patient registrants have been accrued. No detailed results are available yet and the study remains open.

An abstract has been published AACR 27:204 1986.

Detail Summary Sheet

Prot No: POG 8451(86) Status: Ongoing

TITLE: Intergroup Rhabdomyosarcoma - Study III

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatric/Hematology-Oncology Service

Key Words: rhabdomyosarcoma;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Drugs Decision: Continue

OBJECTIVE: This protocol is the new Intergroup Rhabdomyosarcoma III study designed to provide definitive care to all new cases of rhabdomyosarcoma less than 21 years of age.

TECHNICAL APPROACH: Multiagent chemotherapy and radiotherapy tailored to: site of disease, histologic subtype and stage of disease. Results will be compared to IRS I & II (historical controls).

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Six years into the study there have been 1,022 patients registered and 914 are evaluable. A total of 280 patients have completed therapy. There have been 163 deaths (126 tumor related, 8 toxicity related and 25 related to infections). While results are still blinded, there is strong statistical evidence (P .001) of an increasing trend in survival by study. For IRS-I, II, III the estimated percentage of patients surviving three years is 68%, 74% and 82% respectively.

Detail Summary Sheet

Prot No: POG 8552(85) Status: Completed

TITLE: A Case Control Study of Childhood Rhabdomyosarcoma

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: rhabdomyosarcoma;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To evaluate the relationships between environmental exposures, gestational factors, and genetic factors in childhood rhabdomyosarcoma.

TECHNICAL APPROACH: Data will be collected by telephone interview conducted by the Intergroup Rhabdomyosarcoma Group and by a questionnaire. These data will be correlated with biologic data collected from treatment protocol forms.
PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients have been enrolled on this study to date. The study enrolled 365 fully evaluable patients.

Publication: J Clin Oncology 2:670-675, 198'
Med Hypotheses 12:17-20, 1983.
J Natl Cancer Inst 68(1):107-113, 1982

Analysis is currently in progress.

Detail Summary Sheet

Prot No: POG 8600/01/02 (86) Status: Ongoing

TITLE: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia of Childhood (ALinC 14C)

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: leukemia;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To thoroughly classify by laboratory methods the type of leukemia in children newly diagnosed with ALL, to see if better characterization of newly diagnosed leukemia can better define different prognostic groups. To provide comprehensive care of children newly diagnosed with ALL.

TECHNICAL APPROACH: Multiagent chemotherapy of ALL. Results of therapy will be compared to previous POG protocols for therapy of ALL which serve as historical controls. Data will be used to construct new treatment regimens based on prognostic groups and previous therapeutic studies.

PROGRESS: No. of Subjects Enrolled - To Date: 7 Reporting Period: 2

Seven TAMC Pediatric patients enrolled at this time. Fourteen hundred fifty patients have been entered into the treatment portion of the study (8602) nationally. It appears that chromosone Ploidy, is an important prognostic factor. Event free survival for all patients at 18 months follow-up is about 80%.

Publication: Blood 70(6): 1962-1965, 1987
Blood 72(1): 229-307, 1988
Leukemia 2(1): 727, 1988
Annual Reviews of Medicine 40:113 - 122, 1989
PNAS 86: 4254 - 4258, 1989
Science 246: 379 - 382, 1989

POG 8600 has enrolled 2,065 patients nationally the following factors have been found to be prognostic: (1) Within non-T, non-B: White count, age, ploidy, MYIO. (2) Within T: No significant factors. (3) Pre-B is not a significant factor at this time. 8602 Summary: (1) Overall remission induction rate is 97%. (2) Pre-B has not been a significant adverse prognostic factor, no significant difference in event free survival between Arm D and the other arms. (3) CNS relapses are rare; no isolated testicular relapses have yet occurred and marrow relapses are low. (4) Three year event free survival is 80%. (5) Duke MYIO and St. Jude Ploidy are significant prognostic factors for early event free survival. (6) Toxicity concerns have been infections, allergic reactions, transaminase elevations and hematologic suppression.

Detail Summary Sheet

Prot No: POG 8615(90) Status: Ongoing

TITLE: A Phase III Study of Large Cell Lymphomas in Children and Adolescents--A Comparison of Two Treatment Regimens--ACOP+ Versus APO

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators: MAJ Shirley E. Reddoch, MC

Department/Section: Pediatrics/Hemotology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: (1) To determine the influence of cytoxan therapy in advanced stage large cell lymphomas in children and adolescents, by comparing in a randomized prospective study the efficacy and toxicity of a modified ACOP+ versus a modified APO regimen.

(2) To reduce the adverse effects of treatments by eliminating involved field and cranial radiotherapy.

(3) To evaluate the adequacy of one year of total therapy.

TECHNICAL APPROACH:

A (adriamycin) 75 mg/m^2		A (adria) 75 mg/M^2
C (cytoxan) 800 mg/M^2	vs.	P (predrisone) 40 mg/M^2
O (vincristine) 1.5 mg/M^2		O (vincristine) 1.5mg/M^2
P (prednisone) 40 mg/M^2		

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

No TAMC patients are enrolled to date.

Detail Summary Sheet

Prot No: POG 8617/18(87) Status: Ongoing

TITLE: Therapy for B-Cell Acute Lymphoblastic Leukemia and Advanced Diffuse Undifferentiated Lymphomas

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology Oncology Service

Key Words: acute lymphocytic leukemia;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: a. To estimate the complete remission (CR) rate in patients with Stage IV diffuse undifferentiated non-Hodgkin's lymphoma (DU NHL) and B-cell acute lymphocytic leukemia (B-ALL) with a new schedule of administration of three active agents: "split-dose" cyclophosphamide (cyclo) → Adriamycin (Adria) + vincristine (VCR). b. To estimate chemotherapeutic cure rate in State IV DU NHL and B-ALL with a brief (6 months) intensive rotational chemotherapy program designed to confer greater protection against central nervous system (CNS) disease and marrow relapse. c. To estimate the reinduction rate and disease-free survival rate for patients in relapse with non-lymphoblastic lymphoma.

TECHNICAL APPROACH: All patients are treated with four cycles of high dose cytoxan, vincristine, daunomycin plus IT therapy with MTX and ARA-C alternated with 4 cycles of high dose MTX, high dose ARA-C and IT MTX and ARA-C.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 0

Sixty-three patients have been entered on this study nationally with 52 being considered fully evaluable. Complete response rates are 81% for B-ALL and 95% for lymphoma patients. Treatment as delivered under this protocol has resulted in significant improvement in survival for both B-ALL and lymphoma patients (Stage IV-DU NHL) as compared to previous studies. A successor protocol is being developed and a manuscript of this study is being prepared. Toxicity has been encountered including 4 deaths from fungal infectious and one death off therapy from pneumocystis carinii. Reversible myelopathy has also been encountered.

Detail Summary Sheet

Prot No: POG 8625/26(90) Status: Ongoing

TITLE: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA, Hodgkin's Disease in Pediatric Patients

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Pediatric Hematology/Oncology Section

Key Words: Hodgkin's disease

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: (1) To compare the effectiveness of 3 cycles of MOPP/ABVD vs 2 cycles of MOPP/ABVD plus low-dose radiation therapy in terms of duration of remission and eventual survival in children with early stage Hodgkin's disease; (2) To compare the incidence and severity of acute/long-term toxicity of MOPP/ABVD vs MOPP/ABVD plus involved field, low-dose radiation therapy; (3) To evaluate the incidence of CR after 2 cycles of MOPP/ABVD; (4) To search for prognostic factors that may correlate with duration of survival; (5) To determine the salvage rate of patients who fail to respond to 2 cycles of MOPP/ABVD or who fail to achieve a CR after completion of prescribed therapy.

TECHNICAL APPROACH: Pediatric patients under the age of 21 with new diagnoses of early stages of Hodgkin's disease will be eligible. Treatment will be as outlined in the study protocol.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: POG 8631(87) Status: Ongoing

TITLE: Medulloblastoma Favorable Prognosis: Randomized Study of Reduced Dose Irradiation to Brain and Spinal Contents vs. Standard Dose Irradiation

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology/Oncology Service

Key Words: medulloblastoma; radiation;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To see if reduced irradiation to the spinal contents and supratentorial area of the brain can achieve an equal rate of disease-free survival and a lesser degree of psychomotor retardation as compared to standard dose irradiation.

TECHNICAL APPROACH: All registered children will be randomized into one of two treatment arms (a) Arm 1--3600 rads to whole brain and spinal contents plus an additional 1800 rads to posterior fossa, and (b) Arm 2--2340 rads to whole brain and spinal contents plus an additional 3060 rads to posterior fossa.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No Tripler patients have been enrolled in this study. Nationally a total of 48 patients have been registered. Toxicity has been mild. To early in the study to determine statistical differences. Of note, there is a 17% ineligible rate due to poor compliance.

Detail Summary Sheet

Prot No: POG 8633/34(89) Status: Ongoing

TITLE: The Treatment of Children Less Than Three Years of Age with Malignant Brain Tumors Using Postoperative Chemotherapy and Delayed Irradiation

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: postoperative chemotherapy;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if the use of postoperative chemotherapy in children less than 36 months of age with malignant brain tumors will allow for the delay of cranial irradiation for 12 months in children 2-3 years at diagnosis and 24 months for those less than two years old. To estimate the response (CR or PR) to two cycles of cyclophosphamide and vincristine in children with measurable tumor at the initiation of chemotherapy. To estimate the objective response rate (CR, PR, SD) and disease control interval with this multi-agent chemotherapy regimens. To estimate the disease control interval, recurrent-free survival, and survival for children following chemotherapy and radiation therapy in each disease category. To establish the acute and chronic toxicities of this approach, including neurological, neuropsychological, endocrine, and somatic effects.

TECHNICAL APPROACH: Children will be randomized to one of two treatment programs based on age at diagnosis. Chemotherapy will consist of vincristine (.065 mg/kg) and cytoxan (65 mg/kg) alternated with cisplatinum (4 mg/kg) and VP-16 (6.5 mg/kg) as per the attached treatment schema. Upon completion of chemotherapy, children with a complete response will receive radiotherapy. Children with stable disease or a partial response may have a second surgical procedure followed by radiotherapy.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

One TAMC patient enrolled during this evaluation period demonstrated persistent disease following treatment on 8633. He has just completed radiation therapy per POG 8634.

POG November 1989 report indicates 178 patients enrolled as of November 1988; 116 in 0-23 month age group, 56 in 24-36 month age group. Seventy five patients went off study for progressive disease but only 42 were registered on 8634. Overall survival at 2 years are essentially the same for each age group, See attached survival figures to include evaluation by histologic types. It is too early for analysis of response on 8634.

Detail Summary Sheet

Prot No: POG 8638(88) Status: Completed

TITLE: Randomized Phase II Study of Carboplatin (CBDCA) vs CHIP in the Treatment of Children with Progressive or Recurrent Brain Tumors

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: To determine the effectiveness of Carboplatinum and CHIP in the treatment of children with progressive or recurrent brain tumors and to compare the toxicities associated with the use of each agent.

TECHNICAL APPROACH: All patients less than 21 years of age at the time of original diagnosis who now have recurrent or progressive brain tumors are eligible for this study. This study looks to compare the effectiveness and toxicity of carboplatin and CHIP in this group of previously treated patients.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

This protocol was closed effective April 9, 1990. A sufficient number of patients have been accrued to this study to satisfy the study objectives.

Detail Summary Sheet

Prot No: POG 8650(89) Status: Ongoing

TITLE: National Wilms' Tumor Study 4

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Pediatric Hematology/Oncology Section

Key Words: Wilms' tumor;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To compare the relapse-free and overall survival rates of 1) stages I and II FH patients and stage I anaplastic patients treated with conventional CT vs pulse-intensive CT with vincristine and actinomycin D; 2) patients with stage III and IV FH Wilms' and stage I-IV CCSK who are treated with conventional CT vs pulse-intensive CT with vincristine, actinomycin D, and Adriamycin + XRT; 3) patients with stage II-IV anaplastic Wilms' who are treated with vincristine, actinomycin D, and Adriamycin vs those three drugs in combination with cyclophosphamide and XRT; 4) patients with stage II-IV FH and stage I-IV CCSK who are treated for 6 mos vs approximately 15 mos post-nephrectomy.

TECHNICAL APPROACH: Patients with stage I-IV favorable histology (FH) or stage I-IV anaplastic Wilms' tumor, or stage I-IV clear cell sarcoma of the kidney (CCSK). Must have undergone nephrectomy, but no prior CT or XRT. Must be ≤16 yrs of age. Followed: Must have stage I-IV anaplastic Wilms' tumor, stage I-IV CCSK, or stage I-IV malignant rhabdoid tumor of the kidney. Must have a medical or social reason precluding randomization (see Sec. 4.122), including age >16 yrs. Registered: 1) Patients with histologically confirmed mesoblastic nephroma or diagnosis other than Wilms', anaplastic, clear cell, or rhabdoid tumor (to include those patients who have been previously treated or who have died post-op); OR 2) patients who have received prior therapy

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period: 2

Nationally 487 patients have been registered. No statistical analysis available at this time.

Detail Summary Sheet

Prot No: POG 8651(86) Status: Ongoing

TITLE: Osteosarcoma Study #2: A Randomized Trial of Pre-Surgical Chemotherapy vs Immediate Surgery and Adjuvant Chemotherapy in the Treatment of Nonmetastatic Osteosarcoma, Phase III

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatric/Hematology-Oncology Service

Key Words: osteosarcoma; chemotherapy;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Methotrexate Decision: Continue

OBJECTIVE: To compare delayed surgery group to their immediate surgery controls to see if (1) those patients considered ineligible for limb salvage can be converted to candidates for limb salvage, and (2) preoperative chemotherapy improves disease-free survival.

TECHNICAL APPROACH: Multiagent chemotherapy utilizing methotrexate, adriamycin, cis-platinum, Bleomycin, Actinomycin-D and Cytoxan over 42 weeks. One half of patients are randomized to immediate therapy. The remainder receive 10 weeks of adjuvant chemotherapy prior to definitive surgery.

PROGRESS: No. of Subjects Enrolled - To Date: 3 Reporting Period: 0

Three TAMC patients have been enrolled in this study. Toxicity has been primarily hematopoietic. Bleomycin induced (transient) pulmonary toxicity was noted in one patient. Two patients are alive and well with no evidence of active disease. One TAMC patient has died of recurrent disease.

As of POG April 90 report, 62 patients have been registered; 30 to presurgery chemotherapy, 32 to post-operative chemotherapy. Most common toxicities are neutropenia, thrombocytopenia, stomatitis/mucositis and elevated transaminases. Treatment specific response remains masked but overall disease-free survival curve and life table analysis has been provided.

Detail Summary Sheet

Prot No: POG 8696/97(87) Status: Completed

TITLE: Treatment of Hepatoblastoma (HB) with Surgery, Chemotherapy, and Radiation Therapy

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: hepatoblastoma (HB);

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: This is a study directed toward comprehensive care of the child with hepatoblastoma. There is only scattered data on therapy or survival in this relatively rare tumor of childhood. This study will involve single arm studies of each stage of the disease using the anticipated best available therapy for each stage. This study will establish a benchmark for future therapies and explore the importance of several factors including: 1) Histology 2) Modern studying and surgical therapy, 3) Alpha-fetoprotein levels, 4) chemotherapy (cis-platinum, vincristine, 5-FU for 80 days), and 5) Radiotherapy to localized unresectable disease.

TECHNICAL APPROACH: These are single armed studies stratified by stage. There is no randomization.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

Nationally 62 fully evaluable patients are available. All patients with measurable disease have had at least a partial response to chemotherapy. POG 8696: Stage I: one patient has relapsed with AFP negative tumor, three others remain free of disease post surgery.
POG 8697: Stage IIA: 15 patients remain in remission after surgery (27-30 mo), one patient with progressive disease after two courses of chemotherapy. Stage II C: 4 patients are in remission 27 to 30 months from surgery, one death from unrelated causes. Stage III: 12 of 16 patients achieved complete remission with surgery following chemotherapy. They remain disease free 3-30 months post surgery. Two patients achieved only partial remission and went on to liver transplant. One remains alive with progressive disease. Stage IV: 17 evaluable patients. Twelve achieved complete remission with chemotherapy and surgery. Three patients experienced a partial response and two have progressive disease. Stage IV (metastatic disease): two complete response, four partial response and two progressive disease. It is too early to assess survival.

Most patients have experienced grade IV hematologic toxicity. One patient had severe electrolyte problems requiring reduction of cis-platinum.

Detail Summary Sheet

Prot No: POG 8704(89) Status: Ongoing

TITLE: T-Cell #3 Protocol

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Pediatric Hematology/Oncology Section

Key Words: lymphoblastic lymphoma;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: 1) To determine efficacy of multiagent chemotherapy targeted for patients with T-cell malignancies (leukemia and advanced T-cell lymphoblastic lymphoma). 2) To determine value of high dose L-asparaginase in the first phase of maintenance chemotherapy. 3) To study the biology of malignant T-cell disease.

TECHNICAL APPROACH: Common 14 week induction therapy of Vincristine, Prednisone, Cytoxan, Adriamycin, VM-26, Ara-C, Asparaginase and CNS Prophylaxis or treatment followed by randomization to one of two treatment arms: Trt I - 10 nine-week cycles of alternating Cytoxin/Ara-C, Vincristine/Pred/Adriamycin/6-MP, and VM-26/Ara-C Trt II along with L-asparaginase weekly x 20 weeks starting at beginning of maintenance.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

One TAMC patient enrolled to date, subsequently transferred to another POG institution (WRAMC) for continued therapy on protocol.

POG April 1990 report reveals 185 T-cell ALL and 109 lymphoblastic lymphoma patients registered as of Nov 89. Post induction CR is 97% for T-ALL, 96% for T-NHL. Disease free survival at two years (8691/8704 combined) appears superior to LSA_2L_2 + XRT.

Comparison between arms remains masked. Two year disease free survival figure is provided.

Detail Summary Sheet

Prot No: POG 8710(90) Status: Ongoing

TITLE: Simal #5: Protocol for Second Induction and Maintenance in Childhood Acute Lymphoblastic Leukemia

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators: MAJ Shirley E. Reddoch, MC

Department/Section: Pediatrics/Pediatric Hematology/Oncology Section

Key Words: acute lymphoblastic leukemia

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: The major objective is to increase the cure rate in children with acute lymphoblastic leukemia in first bone marrow or bone marrow and extramedullary relapse. Primary objectives: (1) to compare disease-free survival of a regimen including MTX/VM-26 with a control regimen; (2) To compare disease-free survival of a regimen including IFN with a control regimen. Secondary objectives: (1) To estimate and compare remission duration and toxicity in patients receiving either MTX/VM-26 or IFN as continuation therapy components; (2) To determine the prognostic value of clinical and biologic features at relapse including various clinical features, cytogenetics and immunophenotype in all patients and number of Type I Interferon receptors in those receiving IFN; (3) To estimate the frequency of multidrug resistance in leukemia cells at relapse; (4) To characterize oncogene expression in human leukemic cells at relapse.

TECHNICAL APPROACH: Treatment of any patient under 21 years of age at the time of diagnosis with non-T, non-B, acute lymphoblastic leukemia or undifferentiated leukemia on initial classification or non-lymphoblastic non-Hodgkin's lymphoma with first relapse at any time in marrow (>25% blasts) or extramedullary site, excluding isolated CNS disease with prednisone, vincristine, daunomycin, and L-asparaginase over 28 days to achieve marrow remission. All patients will receive VM-26 and Ara-C and some patients will be randomized to receive either VM-26 and methotrexate or interferon to consolidate remission. If remission is achieved, 96 weeks of continuation therapy with 2 or 3 drug combinations will be given. The purpose of this study is to achieve remission and compare ability of different combination or drug combinations plus interferon to prolong remission.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: POG 8725(88) Status: Ongoing

TITLE: Randomized Study of Intensive Chemotherapy (MOPP/ABVD) + Low-Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, $IIIA_2$, IIIB, IV Hodgkin's Disease in Pediatric Patients

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: total nodal radiation therapy (TNRT);

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: a. To determine, in a randomized study, whether the addition of low-dose total nodal radiation therapy (TNRT) in pediatric patients with Hodgkin's disease who have achieved a complete remission after receiving 4 courses of MOPP alternating with 4 courses of ABVD will improve the duration of complete remission and survival when compared to patients who have received chemotherapy alone. b. To determine whether TNRT will significantly (i.e., grade 3 or 4) increase either acute toxicity or long-term morbidity when compared to MOPP/ABVD alone. c. To determine the effect of chemotherapy as compared to chemotherapy plus TNRT on splenic function as determined by the pitted erythrocyte count using Nomarski optics.

TECHNICAL APPROACH: Randomized treatment study (National protocol). Following chemotherapy of MOPP/ABVD, those patients assessed to be disease free will be equally randomized to TNRT or no further therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

POG April 90 report indicates 69 patients enrolled through Nov 1989. Limited response data available. Too early for toxicity or survival assessment. However, five patients have died, three of progressive disease and two of overwhelming sepsis while in remission.

Detail Summary Sheet

Prot No: POG 8739(88) Status: Ongoing

TITLE: Evaluation of Alpha Interferon in the Treatment of Recurrent Brain Tumors in Children - a Phase II Study

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Alpha-Interferon Decision: Continue

OBJECTIVE: To determine the efficacy of alpha$_2$-interferon (α-IFN) in children with recurrent brain tumors resistent to standard therapy in regard to response rate of different histologic subtypes to α-IFN, and to further assess the toxicity of α-IFN in children.

TECHNICAL APPROACH: Treatment of recurrent brain tumors in children

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

With regard to the master protocol, strata 1, 2, 4, 5 and 6 will close effective 5/15/90 as a result of insufficient patient accrual; however, strata 3 remains open (i.e., the patients accepted into this study are those with medulloblastomas).

Detail Summary Sheet

Prot No: POG 8741/42(87) Status: Ongoing

TITLE: Treatment of Stage D Neuroblastoma in Children Greater Than or Equal to 365 Days at Diagnosis

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: neuroblastoma;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: This study is designed to look specifically at children in the worst prognostic groups of neuroblastoma. This study will employ four phase two agents in addition to standard chemotherapy.

TECHNICAL APPROACH: Children will be randomized to receive one of 4 phase two agents as initial drug therapy. After two courses they will then be randomized to one of two standard treatment arms for completion of therapy. Results will be compared to historical group controls.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

POG April 90 report indicates 154 patients enrolled on POG 8741 and 147 on POG 8742 as of Nov 1988. Treatment specific induction response rates are masked but across all arms for the 184 evaluable patients PR is 37%, MR is 14%, No response is 29%. Most severe toxicity remains neutropenia and thrombocytopenia. The POG 8742 survival curve and life table for all patients is provided.

Detail Summary Sheet

Prot No: POG 8743(88) Status: Ongoing

TITLE: Treatment in "Better Risk" Neuroblastoma: POG Stage B (All Ages), and POG Stage C, D, and DS (IVS) 365 Days

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: a) To prospectively identify, by flow cytometric DNA index, patients 365 days of age at diagnosis who will fail to achieve complete remission (CR) with cyclophosphamide (CYC) and Adriamycin (ADR) and delayed surgery; then to alter therapy in these patients and evaluate the CR and survival rates with alternate therapy, using cis-platinum (CDDP) and VM-26.
b) To evaluate the disease-free survival (DFS) and survival in a larger group of patients currently considered to be "better risk" patients with neuroblastoma.
c) To evaluate DFS and survival in a larger group of infants with DS disease (Stage IV-S) observed without therapy versus those treated with CYC-ADR.
d) To evaluate the prognostic value of LDH at diagnosis, N-myc gene amplication in tumor at diagnosis, GD_2 level in tumor and serum at diagnosis, and serum neuron-specific enolase (NSE) and serum ferritin at diagnosis.

TECHNICAL APPROACH: The therapy of all children less than 21 years of age with neuroblastoma and children less than 365 days of age with Stage C, D, and IVS disease.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Closure/completion is expected in early FY91.

Detail Summary Sheet

Prot No: POG 8759(88) Status: Ongoing

TITLE: The Effectiveness of Phase II Agents in Untreated Metastatic Osteosarcoma (MOS) or Unresectable Primary Osteosarcoma vs Previously Treated Osteosarcoma

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: a) To estimate the response rate to Ifosfamide in patients presenting with metastatic osteosarcoma or unresectable primary osteosarcoma prior to treatment of those patients with other chemotherapeutic reagents.
b) To estimate the response rate to Ifosfamide in previously treated patients with osteosarcoma.
c) To explore the feasibility and toxicity of the addition of Ifosfamide to a multi-agent combination chemotherapy regimen which includes drugs known to be active in the treatment of osteosarcoma. If the regimen can be given without excessive toxicity and if the regimen is effective, it will be explored further as frontline treatment for patients presenting without metastases.
d) To study the DNA content of primary and metastatic tumors.

TECHNICAL APPROACH: Treatment of previously untreated patients with metastatic osteosarcoma or unresectable primary osteosarcoma.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

There are 44 fully-evaluable patients entered into this study. The disease-free survival on all of these patients is about 45% at 33 months.

Detail Summary Sheet

Prot No: POG 8763(90) Status: Ongoing

TITLE: Evaluation of Response and Toxicity of Ifosfamide and VP-16-213 in Children with Resistant Malignant Tumors

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Pediatric Hematology/Oncology

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine the antitumor activity and toxicity of ifosfamide plus VP-16 against malignant solid tumors resistant to conventional chemotherapy.

TECHNICAL APPROACH: VP-16 100 mg/M^2/d x 3 day
Ifosfamide 2.0 gm/M^2/d x 3 days + (Mesna/uroprotection)
Repeat every 14 - 21 days as peripheral counts permit. Total therapy time is 18 months or until there is evidence of progressive disease.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

No TAMC patients enrolled.

Detail Summary Sheet

Prot No: POG 8764(88) Status: Ongoing

TITLE: Chemotherapy Regimen for Early and Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia - A Pediatric Oncology Group Phase II Study

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: lymphoblastic leukemia

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To estimate the complete remission rate for early and initial induction failures in childhood ALL based on an induction regimen of VM-26 and continuous infusion cytosine arabinoside (Ara-C); to estimate the one-year disease-free survival for early and initial induction failures in childhood ALL, based on a new regimen; to try and better characterize this unique subpopulation of patients with primary drug resistance using cDNA probes for the multidrug-resistant phenotype and obtain an oncogene profile.

TECHNICAL APPROACH: Remission induction with standard dose continuous ARA-C, high dose VM-26 and TIT. Continuation therapy with MTX, ARA-C, VM-26, Daunomycin adn 6-MP.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

POG April 90 report reveals slower than expected patient accrual with only 12 patients enrolled to date (6 patient 'years vs projected 9/yr). Response is masked. No unexpected toxicity.

Detail Summary Sheet

Prot No: POG 8820(90) Status: Ongoing

TITLE: VP-16, AMSA + 5-Azacytidine in Refractory ANLL (A POG Randomized Phase II/III Study)

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Pediatric Hematology/Oncology

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: (1) To compare, in a randomized study, the remission rate of VP-16/AMSA vs. VP-16/AMSA/5-AZA in children with recurrent or refractory acute non lymphocytic leukemia.
(2) To determine the duration of remission, using pulses of the induction regimen as continuation therapy.
(3) To study the relative toxicities of these two therapies.

TECHNICAL APPROACH: (A) AMSA 100mg/M^2/d x 5 days + VP-16 200mg/M^2/d x 2 days (B) Treatment A above plus 5-AZA 250mg/M^2 on day 4 & 5.

One or two courses for remission induction followed by 10 courses of maintenance.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

No TAMC patients enrolled at this time.

Detail Summary Sheet

Prot No: POG 8821(88) Status: Ongoing

TITLE: AML#3: Intensive Multiagent Therapy vs. Autologous Bone Marrow Transplant Early in First CR for Children with Acute Myelocytic Leukemia

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: acute myelocytic leukemia;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: a) To determine the disease-free survival (DFS) and event-free survival (EPS) in childhood acute myelocytic Leukemia (AML) offered by intensive chemotherapy with alternating non-cross resistant drug combinations for nine courses. b) To determine if short (three course) intensive chemotherapy (identical to the first three courses of the above regimen) followed by autologous bone marrow transplant (BMT) using the Busulfan/ Cytoxan preparative regimen and 4-Hydroperoxycyclophosphamide (4-HC) purged marrow is effective therapy, c) To compare, in a randomized study, the results of the above two regimens. d) To correlate the treatment outcome with clinical and laboratory features.

TECHNICAL APPROACH: Patients to be equally randomized (after remission induction with 6-TG, ARA-C and Daunomycin to standard chemotherapy for maintenance or autologous bone marrow with 4-HC purging and no further therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

POG April 1990 report reveals 178 patients enrolled through Dec 1988. CR achieved in 84.8% patients with data sufficient for evaluation. Treatment response still masked by statistical office. No unusual toxicity except 7 of 145 (4.1%) receiving high dose ARA-X developed cerebellar toxicity.

Detail Summary Sheet

Prot No: POG 8823/24 (90) Status: Ongoing

TITLE: Recombinant Alpha-Interferon in Childhood Chronic Myelogenous Leukemia

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Pediatric Hematology/Oncology

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: (1) To determine toxicity, response rate and duration of response to therapy with recombinant alpha interferon for newly diagnosed "adult" CML in chronic phase, and for "juvenile" CML occurring within the first two decades.
(2) To obtain prospective clinical, laboratory and genetic data on cases of adult and juvenile CML treated with v-alpha interferon.

TECHNICAL APPROACH: After diagnostic materials are collected, patients are treated with 24 million u/M^2 r-alpha interferon x 14 days then Q O D x 90 days. Patients are then evaluated for further maintenance or off therapy. Transplant may be performed at any time.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

One TAMC patient enrolled to date.

Detail Summary Sheet

Prot No: POG 8828(90) Status: Ongoing

TITLE: Late Effects of Treatment of Hodgkin's Disease

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Pediatric Hematology/Oncology Section

Key Words: Hodgkin's disease

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts; Decision: Continue

OBJECTIVE: Primary: (1) To estimate the incidence of various late effects seen in patients with Hodgkin's disease treated by the regimens of POG #8625/26 and POG #8725; (2) To compare the two treatment arms of POG #8625/26 and the two treatment arms of POG #8725 for the incidence of the above late effects. Secondary: (1) To attempt to identify disease and treatment-related factors and post-treatment factors which contribute to specific late effects; (2) To attempt to identify pre-treatment factors, on-treatment and/or post-treatment factors which predict high risk of specific late effects.

TECHNICAL APPROACH: Patients will participate either in POG #8625 ("early stage" Hodgkin's disease) or POG #8725 ("late stage" Hodgkin's disease) therapeutic studies. Data will be obtained to help identify patients long-term follow-up needs, particularly earlier recognition and management of high-incidence treatment toxicities. Should treatment arms of the therapeutic Hodgkin's protocols (8625/26 and 8725) produce equivalent disease responses, this long-term toxicity date will be critical in the determination of the "better" treatment arm.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: POG 8832(90) Status: Ongoing

TITLE: Pre-Irradiation Chemotherapy in Supratentorial Malignant Tumors

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Pediatric Hematology/Oncology Section

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: (1) To determine, acute, subacute and combined-treatment . . toxicities of chemotherapy with cisplatin and ARA-C followed by cranial irradiation in children.
(2) To estimate the efficacy of a 15 week period of chemotherapy with cisplatin and ARA-C in children with malignant supratentorial (primary CNS) tumors.
(3) To estimate the feasibility and completeness of second surgical resection in children with incompletely resected supratentorial tumors after treatment with initial chemotherapy.

TECHNICAL APPROACH: All patients must have diagnostic biopsy. Chemotherapy every three weeks for five courses. Patients will then procede to a second resection and/or standard radiation therapy. Full evaluation will occur at week 70 or earlier as clinically indicated.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

No TAMC patients enrolled at this time.

Detail Summary Sheet

Prot No: POG 8850(89) Status: Ongoing

TITLE: Evaluation of Vincristine, Adriamycin, Cyclophosphamide, and Dactinomycin with or without the Addition of Ifosfamide and Etoposide in the Treatment of Patients with Newly-Diagnosed Ewing's Sarcoma or Primitive Neuroectodermal Tumor of Bone: A Phase III Intergroup Study

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Pediatric Hematology/Oncology Section

Key Words: Ewing's sarcoma;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: Primarily: To determine and compare the EFS of patients treated with VP-16 and Ifosfamide in addition to standard therapy vs treatment with standard therapy alone. Secondarily: a) Evaluate toxicities and adverse orthopedic outcomes associated with disease and therapies; b) Assess significance of tumor site, size, histology and EM pattern in determining outcome; c) Correlate imaging characteristics with response, prognosis, RT adequacy, and survival; d) Assess prognostic value of cellular DNA content and chromosome changes.

TECHNICAL APPROACH: Patients with newly diagnosed Ewing's sarcoma or PNET of bone will be evenly randomized to one of two treatment arms: Reg A-52 week course of chemo including Vincristine, Adriamycin, Cytoxan, Actinomycin D with surgery and/or XRT as needed (standard therapy). Reg B-52 week including Ifosfamide and Etoposide as well as therapy employed in Regimen A.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

POG April 1990 report reveals 62 patients accured. No results reported to date. Response masked by statistical office.

Detail Summary Sheet.

Prot No: POG 9047(90) Status: Ongoing

TITLE: Neuroblastoma Biology Protocol

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Pediatric Hematology/Oncology Section

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To characterize the biological nature of neuroblastoma.

TECHNICAL APPROACH: Referral of fresh unfixed tumor material plus serum and plasma to POG reference laboratories.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

No Tripler patients have been enrolled to date. Nationally no information is available at this time.

Detail Summary Sheet

Prot No: POG 9082(90) Status: Ongoing

TITLE: Protocol for the Development of Intervention Strategies to Reduce the Time Between Symptom Onset and Diagnosis of Childhood Cancer

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators: MAJ Shirley E. Reddoch, MC

Department/Section: Pediatrics/Pediatric Hematology/Oncology Section

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: (1) To describe the constellation of signs and symptoms which occur prior to the definitive diagnosis of childhood cancer; (2) To evaluate factors which may be associated with the length of time between the onset of symptoms and diagnosis; (3) To determine if the pattern of symptoms and the length of time between symptom onset and diagnosis influence prognosis independent of treatment and the stage of disease at diagnosis; (4) To provide information which may be used to develop intervention strategies aimed at reducing the interval between onset of symptoms and diagnosis.

TECHNICAL APPROACH: All patients at the time of registration on a POG frontline therapeutic protocol will be surveyed for historical information regarding signs/symptoms and illness duration preceding diagnosis of cancer. This data will be analyzed for information which may be used to develop intervention strategies designed to reduce the interval between onset of illness and diagnosis with the intent to improve long-term diagnosis.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: CRCH 8900(90) Status: Ongoing

TITLE: Efficacy and Safety Trial of Toremifene vs Tamoxifen in Postmenopausal Patients with Metastatic Breast Cancer

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William Uphouse, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS; LTC Lawrence Sakas, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: Toremifene; Tamoxifen; breast cancer

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To compare the efficacy and side effects of tamoxifen and toremifene (at 2 different dose levels) in postmenopausal patients with metastatic breast cancer.

TECHNICAL APPROACH: Patients will be randomized to (1) tamoxifen 10mg twice a day p.o.; (2) toremifene 60mg once a day p.o.; or (3) toremifene 200mg once a day p.o.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period: 0

This study opened recently and there are no data available yet.

Detail Summary Sheet

Prot No: CRCH 8901(89) Status: Ongoing

TITLE: Cancer Research Consortium of Hawaii - Phase II Evaluation of Hepatic Chemoembolization with Angiostat Collagen and Cisplatin, Mitomycin and Doxorubicin

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC

Department/Section: Medicine/Medical Hematology-Oncology Service

Key Words: hepatic chemoembolization; doxorubicin;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine the efficacy of chemoembolization in unresectable metastatic tumors to the liver and primary hepatoma.

TECHNICAL APPROACH: Patients agreeing to participate will undergo hepatic artery catheterization for chemoembolization of the part of the liver. A second and subsequent chemoembolization will be done at intervals of 2 to 4 weeks to treat the rest of the liver.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study opened recently and there are no available data yet.

Detail Summary Sheet

Prot No: CRCH 8903(89) Status: Ongoing

TITLE: A Multicenter Phase II Trial of Intravenous PEG-Interleukin-2 (Modified Recombinant Human) (PEG IL-2) in Patients with Advanced Renal Cell Carcinoma

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC

Department/Section: Medicine/Medical Hematology-Oncology Service

Key Words: Interleukin-2;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine the response rate to PEG IL-2 in patients with advanced renal cell carcinoma.

TECHNICAL APPROACH: Patient agreeing to participate will receive PEG IL-2 over 15 minutes IV weekly for 8 weeks and then be reassessed for further treatment depending on their response. The patients will be hospitalized for 24 hours after the first dose to monitor for toxicity.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study opened recently and there are no available data yet.

Detail Summary Sheet

Prot No: CRCH 8904 (90) Status: Ongoing

TITLE: ADR-529 as a Cardioprotective Agent in a Phase III Randomized Trial of FAC vs FAC + ADR-529 in the Treatment of Disseminated Carcinoma of the Breast

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine if ADR-529 has a cardioprotective effect when added to Adriamycin-based chemotherapy in patients with disseminated breast cancer.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1) FAC chemotherapy day 1 every 3 weeks or 2) FAC chemotherapy plus ADR-529 IV bolus day 1 every 3 weeks.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

This study opened recently and no data are available.

Detail Summary Sheet

Prot No: CRCH 8905 (90) Status: Ongoing

TITLE: Daily Treatment of Myelodysplastic Syndrome (MDS) with Oral Idarubicin

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine if treatment with oral Idarubicin can result in improvement in hematologic parameters in patients with poor prognosis myelodysplastic syndrome.

TECHNICAL APPROACH: Patients agreeing to participate will receive p.o. Idarubicin daily for 21 days out of each 28 days. Treatment for 6 months total is planned.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study opened recently and no data are available.

Detail Summary Sheet

Prot No: NSABP B15(84) Status: Completed

TITLE: A Three-Arm Clinical Trial Comparing Short Intensive Chemotherapy With or Without Reinduction Chemotherapy to Conventional CMF in Receptor-Negative Positive-Node Breast Cancer Patients

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William Uphouse, MC; LTC Joseph Woods, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: breast cancer;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To determine if a short course of chemotherapy in the adjuvant setting is as effective as the "standard" six months of CMF. Also, to determine if a later "reinduction" will improve survival.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to one of three treatment groups: (1) Adriamycin and Cytoxan for four cycles, (2) Adriamycin and Cytoxan as above, then, after six months of rest, three cycles of CMF, or (3) six cycles of CMF ("standard" therapy).

PROGRESS: No. of Subjects Enrolled - To Date: 4 Reporting Period: 0

Patients entered to date at TAMC are doing well. The results of this trial were just published in the September, 1990 issue of the Journal of Clinical Oncology. So far there is no difference in relapse rate or survival among the three arms of the study. With more follow up time further results will be forthcoming.

Detail Summary Sheet

Prot No: NSABP B17(86) Status: Ongoing

TITLE: A Clinical Trial to Evaluate Natural History and Treatment of Patients with Noninvasive Intraductal Adenocarcinoma

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; LTC Aida P. Ronquillo, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: adenocarcinoma, noninvasive intraductal;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine whether lumpectomy is an effective operation for the treatment of noninvasive breast cancer and if radiation treatments add to that effectiveness.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be randomized after lumpectomy to receive or not receive radiation therapy to the involved breast.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

There are no national data available yet about this study except that 581 patients have been entered so far.

Detail Summary Sheet

Prot No: NSABP B18(89) Status: Ongoing

TITLE: A Unified Trial to Compare Short Intensive Preoperative Systemic Adriamycin Cyclophosphamide Therapy with Similar Therapy Administered in Conventional Postoperative Fashion

Principal Investigator: COL Jeffrey L. Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: adriamycin; cyclophosphamide;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine whether 4 courses of preoperative chemotherapy will more effectively prolong disease-free survival and survival than the same 4 courses of chemotherapy given postoperatively in patients with operable breast cancer.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 4 cycles of adriamycin and cytoxan (day 1 IV every 3 weeks) preoperatively or to receive the same 4 cycles of chemotherapy postoperatively. Tamoxifen will be given twice a day after surgery to all patients age 50 years or more (regardless of which chemotherapy group they are assigned).

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 2

This study is still accruing patients and no results are available except that nationally there have been no toxic deaths and toxicity is primarily nausea and vomiting on the day of treatment in 45% of the patients.

Detail Summary Sheet

Prot No: NSABP B19(89) Status: Completed

TITLE: A Clinical Trial to Compare Sequential Methotrexate 5-Fluorouracil (M-F) with Conventional CMF in Primary Breast Cancer Patients with Negative Nodes and Estrogen Receptor Negative Tumors

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words: methotrexate; 5-fluorouracil;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: To determine if 6 cycles of Cyclophosphamide, Methotrexate and 5-fluorouracil is as effective or more effective than 6 cycles of sequential Methotrexate, 5-fluorouracil followed by Leucovorin in the prolongation of disease-free survival and survival in resected, node negative breast cancer.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized post-op to receive either 1) 6 cycles of Cyclophosphamide, Methotrexate and 5-fluorouracil or 2) 6 cycles of sequential Methotrexate 5-fluorouracil (with Leucovorin).

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

This study accrued patients very rapidly and has achieved its targeted number of patients. Toxicity was mild and publication of results is expected shortly.

Detail Summary Sheet

Prot No: NSABP B20(89) Status: Ongoing

TITLE: A Clinical Trial to Determine the Worth of Chemotherapy and Tamoxifen over Tamoxifen Alone in the Management of Patients with Primary Invasive Breast Cancer, Negative Axillary Nodes and Estrogen Receptor Positive Tumors

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words: tamoxifen;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine if Methotrexate plus 5-fluorouracil plus Leucovorin plus Tamoxifen is more effective in terms of disease-free survival and survival than Tamoxifen alone in node negative estrogen receptor positive resected breast cancer. Also to determine if Cyclophosphamide plus Methotrexate plus 5-fluorouracil (CMF) plus Tamoxifen is more effective than Tamoxifen alone. Finally, to compare the 2 chemo programs to each other.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1) Tamoxifen alone for 5 years, 2) Methotrexate, 5-fluorouracil and Leucovorin every 4 weeks for 6 cycles + Tamoxifen as above, or 3) CMF every 4 weeks for 6 cycles + Tamoxifen as above.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

The only national data available concern toxicity. Toxicity has been mild in all arms of the study. The one TAMC patient is doing well on treatment.

Detail Summary Sheet

Prot No: NSABP B-22(89) Status: Ongoing

TITLE: A Clinical Trial to Evaluate the Effect of Dose Intensification and Increased Cumulative Dose of Postoperative Adriamycin-Cyclophosphamide (AC) Therapy on the Disease-Free Survival and Survival of Patients with Primary Breast Cancer and Positive Axillary Nodes

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS; LTC Yeu-Tsu Margaret Lee, MC; MAJ Marianne M. Young, MC

Department/Section: Medicine/Medical Hematology-Oncology Service

Key Words: adriamycin-cyclophosphamide (AC);

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine whether giving larger doses of CTX is the first 2 or 4 cycles of adjuvant CTX and ADRIA chemotherapy will improve the survival of breast cancer patients over patients given standard doses of those 2 drugs for 4 cycles. To determine if larger doses of CTX in all 4 cycles is superior to 4 cycles at standard doses.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1 of 3 dose schedules of CTX and ADRIA IV day one every 3 weeks for 4 cycles (i.e., 12 weeks). Patients age 50 and over will also receive Tamoxifen 10 mg p.o. twice daily for 5 years.

PROGRESS: No. of Subjects Enrolled - To Date: 5 Reporting Period: 5

This protocol opened recently and no national data are available. The TAMC patients have completed their treatment, but increased nausea and vomiting requiring potent anti-emetics were noted with the higher dose cyclophosphamide arms.

Detail Summary Sheet

Prot No: SWOG 7804(84) Status: Ongoing

TITLE: Adjuvant Chemotherapy with 5-FU, Adriamycin and Mitomycin C (FAM) versus Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William Uphouse, MC; COL Peter J. Barcia, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: gastric adenocarcinoma

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine whether or not chemotherapy (FAM) given to patients with advanced but resected gastric carcinoma will prevent relapses and prolong life.

TECHNICAL APPROACH: Patients will be randomized to either (1) receive chemotherapy with FAM twice a month for 1 year or (2) receive no treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

National accrual continues and completion of this study will hopefully be in the near future. Toxicity has been tolerable with some nausea and vomiting (reversible) and some hematologic toxicity (reversible). Of the 193 patients on the study there were 2 deaths possibly related to chemotherapy. One was due to congestive heart failure but the patient appeared to actually have had a myocardial infarction. The other was due to hemolytic-uremia syndrome, an unusual complication of mitomycin-c.

Detail Summary Sheet

Prot No: SWOG 8312(85) Status: Ongoing

TITLE: Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine Therapy of Metastatic Breast Cancer, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: MAJ William Uphouse, MC; LTC Joseph Woods, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: breast cancer, metastatic

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if combined hormone therapies are superior to single hormone therapy in sequence for metastatic breast cancer.

TECHNICAL APPROACH: All patients agreeing to this study will be randomized to one of three treatments: (1) megestrol acetate, (2) aminoglutethimide plus hydrocortisone, or (3) megestrol acetate plus aminoglutethimide plus hydrocortisone.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

There are no TAMC patients on this study. Study remains open with no unanticipated toxicity. Accrual is adequate (233 nationally).

Detail Summary Sheet

Prot No: SWOG 8326/27(85) Status: Ongoing

TITLE: Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blast Crisis, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William Uphouse, MC; MAJ Luke M. Stapleton, MC; MAJ Lawrence Sakas, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: leukemia, adult acute; leukemia, chronic granulocytic

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine the response and response duration of a high-dose program of Ara-C in patients with relapsed acute leukemia.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive (1) six days of high dose Ara-C, (2) the same Ara-C plus three days of m-AMSA, or (3) the same Ara-C plus three days of Mitoxantrone.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 1

Accrual has been slow nationally to date but continues. High dose Ara-C continues to be the most promising drug in relapsed leukemia. One TAMC patient registered on this study achieved a complete remission of her leukemia and did well for 9 months but then relapsed and died. A second TAMC patient did not achieve a complete remission and died. Nationally, the arm (2) with m-AMSA was terminated previously due to 9 deaths among 39 patients. So far, 168 patients nave been entered into the other induction arms. Fatal toxicities have been seen in 5 of 73 patients on arm (1) and 4 of 67 on Arm (3). No response or survival data is available yet.

Detail Summary Sheet

Prot No: SWOG 8393(84) Status: Ongoing

TITLE: National Intergroup Protocol for Intermediate Thickness Melanoma

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William Uphouse, MC; COL Peter J. Barcia, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: melanoma

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: (1) To determine the optimal surgical margins (2 versus 4 cm) around the intermediate thickness melanomas (1-4 mm) that are being resected for cure. (2) To evaluate the value of elective regional lymph node dissection in these same melanomas.

TECHNICAL APPROACH: Patients with primary melanomas of the head or neck or distal extremities will be randomized to receive or not receive elective node dissection, but all patients in this group will have 2 cm surgical margins. Patients with melanomas of the trunk or proximal extremities will undergo two randomizations, (1) to receive or not to receive elective node dissection, and (2) to have either a 2 or 4 cm surgical margin.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 0

Two Tripler patients have been registered on this protocol. It is too early to assess efficacy of this protocol approach. Nationally, 707 patients have been registered. No other data is available.

Detail Summary Sheet

Prot No: SWOG 8417/19(85) Status: Ongoing

TITLE: Evaluation of the Consolidation Regimens in the Treatment of Adult Acute Lymphoblastic Leukemia, Phase III

Principal Investigator: COL Jeffrey L. Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; MAJ Lawrence Sakas, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: leukemia, lymphoblastic

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To compare two consolidation chemotherapy programs in terms of remission, duration, and survival.

TECHNICAL APPROACH: All patients agreeing to participate will be randomized to receive either the L-10M consolidation or the new (shorter) consolidation program.

PROGRESS: No. of Subjects Enrolled - To Date: 5 Reporting Period: 1

This study is the frontline study for patients with newly diagnosed acute lymphoblastic lymphoma and remains open. Of the 5 TAMC patients entered on this study, all 5 entered complete remission but one has relapsed. Nationally, only toxicity data is available. Of 296 patients available for induction toxicity, 25 (81%) had treatment-related deaths. This is not unexpected in leukemia induction chemotherapy.

Detail Summary Sheet

Prot No: SWOG 8516(86) Status: Ongoing

TITLE: A Phase III Comparison of CHOP vs m-BACOD vs ProMACE-CytaBOM vs MACOP-B in Patients with Intermediate and High-Grade Non-Hodgkin's Lymphoma

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: MAJ William J. Uphouse, MC; LTC Lawrence Sakas, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: lymphoma, non-Hodgkin's

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine which of the four leading chemotherapy programs for aggressive lymphomas is best in terms of response, survival, and toxicity.

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to receive one of the four treatment programs listed above.

PROGRESS: No. of Subjects Enrolled - To Date: 3 Reporting Period: 1

We have been slow to accrue non-Hodgkin's cases because these cases have been relatively uncommon hospital-wide. Of the 3 patients entered on this study one went into complete remission, one has relapsed and another patient is being followed at another institution (on the mainland). Only toxicity data is available nationally. The major toxicity has been leucopenia and, given the intensity of these programs, fatal toxicities have ranged from 2-3-1 with CHOP and ProMACE-CytaBOM to 5-6-1 with m-BACOD and MACOP-B.

Detail Summary Sheet

Prot No: SWOG 8530(86) Status: Completed

TITLE: Efficacy of Prednisone in Refractory and Relapsing Multiple Myeloma and Measurement of Glucocorticoid Receptors, Phase II

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William Uphouse, MC, MAJ Luke Stapleton, MC; Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: myeloma; glucocorticoid receptors

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: none Decision: Completed

OBJECTIVE: To estimate the response rate and duration of response with high dose prednisone in patients with refractory myeloma.

TECHNICAL APPROACH: Patients agreeing to participate will receive 100 mg of prednisone every other day for two weeks, then 50 mg every other day for ten weeks.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

This protocol was approved in September 1986. The one patient entered at Tripler has had an excellent response to this therapy, and remains in an excellent partial remission for almost 3 years. Nationally, partial remissions were seen in 10% of 124 patients. Median survival was 12 months. Toxicity was very mild,

Detail Summary Sheet

Prot No: SWOG 8569(87) Status: Completed

TITLE: Therapy of Metastatic Malignant Melanoma with Recombinant Human Interleukin 2, Phase II

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC;
MAJ Luke M. Stapleton, MC;
CPT Scott Martin, MS; LTC Lawrence Sakas, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Completed

OBJECTIVE: To determine the response rate and duration of response of metastatic malignant melanoma to treatment with recombinant human interleukin 2 (IL-2).

TECHNICAL APPROACH: Patients agreeing to participate in the study will receive the interleukin 2 three times a week by IV bolus for 12 weeks and then be reassessed for further IL-2 depending upon their response.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Detail Summary Sheet

Prot No: SWOG 8590(85) Status: Terminated

TITLE: Phase III Study to Determine the Effect of Combining Chemotherapy with Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William Uphouse, MC;

Department/Section: Medicine/Hematology-Oncology Service

Key Words: carcinoma, squamous cell

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: To determine if adding chemotherapy will improve results of surgery and radiation for advanced (Stage III and IV) but resectable head and neck cancer.

TECHNICAL APPROACH: All patients agreeing to participate in the study will be randomized to receive (1) surgery, then radiation therapy, or (2) surgery, then three cycles of chemotherapy (cisplatinum plus 5-FU), then radiation.

PROGRESS: No. of Subjects Enrolled - To Date: 3 Reporting Period: 0

Of the 3 patients entered on this study to date, one received chemotherapy and is doing well. A second patient didn't receive treatment and relapsed, and a third patient left the island unexpectedly and has been lost to followup. This study was terminated as it reached its target patient accrual (696 patients). Toxicity has not been great and there have been no toxic deaths. Results of the study should be available soon.

Detail Summary Sheet

Prot No: SWOG 8598(87) Status: Ongoing

TITLE: A Prospective Trial for Localized Cancer of the Esophagus: Comparing Radiation as a Single Modality to the Combination of Radiation and Chemotherapy, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC;
MAJ Luke M. Stapleton, MC;
CPT Scott Martin, MS; LTC Lawrence Sakas, MC;

Department/Section: Medicine/Hematology-Oncology Service

Key Words: esophagus; cancer; radiation; chemotherapy;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: none Decision: Continue

OBJECTIVE: To determine the role of chemotherapy for a potentially curable subset of patients with squamous cell cancer of the esophagus. Specifically, to determine if the combination of chemotherapy and radiation will add to the overall survival and cure of patients treated with the combination when compared to patients treated by radiation alone.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive (1) radiation alone (6400 rads in 6½ weeks) or (2) radiation (5,000 rads in 5 weeks) beginning simultaneously with four cycles of chemotherapy (cisplatinum plus 5-FU).

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

One patient from Tripler entered. He was randomized to radiation alone, has completed treatment, but died about 8 months later due to recurrent disease. Nationally, no results are available, except that there have been no life-threatening toxicities among the 91 patients treated to date. Toxicity has been primary esophagitis.

Detail Summary Sheet

Prot No: SWOG 8600(87) Status: Ongoing

TITLE: A Randomized Investigation of High Dose Versus Standard Dose Cytosine Arabinoside With Daunorubicin In Patients With Acute Non-Lymphocytic Leukemia

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC;
MAJ Luke M. Stapleton, MC;
CPT Scott Martin, MS; LTC Lawrence Sakas, MC;

Department/Section: Medicine/Hematology-Oncology Service

Key Words: cytosine arabinoside and daunorubicin

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To compare, among patients with acute non-lymphocytic leukemia, the rate of complete remission produced by induction regimens of either standard dose cytosine arabinoside and daunorubicin or high dose cytosine arabinoside and daunorubicin. Also to compare these 2 programs when used in the consolidation phase.

TECHNICAL APPROACH: Patients are randomized to receive standard or high dose cytosine arabinoside initially. If remission is achieved then patients are randomized again to receive standard or high dose cytosine arabinoside for consolidation.

PROGRESS: No. of Subjects Enrolled - To Date: 6 Reporting Period: 2

Of the 6 TAMC patients enrolled on this study in 1988-89, 4 achieved a complete remission. Nationally there are no data yet on response but of 536 patients evaluable for induction toxicity, 33 died as a result of therapy. Due to the toxic nature of leukemia treatment in general, this figure is probably not high.

Detail Summary Sheet

Prot No: SWOG 8614(90) Status: Ongoing

TITLE: Chemotherapy of gastric cancer with VM-26, Phase II

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine the response rate and response duration in patients with advanced gastric cancer treated with VM-26.

TECHNICAL APPROACH: Patients agreeing to participate will all receive VM-26 IV over 45 minutes daily for 5 consecutive days every 3 weeks (until tumor progression).

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

New start.

Detail Summary Sheet

Prot No: SWOG 8616(87) Status: Ongoing

TITLE: Intergroup Phase III Randomized Study of Doxorubicin and Dacarbazine With or Without Ifosfamide and Mesna in Advanced Soft Tissue and Bone Sarcoma

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: ifosfamide; mesna

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if adding ifosfamide and mesna to the usually employed drugs of doxorubicin and dacarbazine will improve the response rate, response duration and survival in metastatic soft tissue and bone sarcoma.

TECHNICAL APPROACH: Patients agreeing to participate will have a central line (port-a-cath) placed and receive 4 days of doxorubicin and dacarbazine continuously through this line. These patients will also be randomized to receive or not receive 4 days of therapy with ifosfamide and mesna. These latter drugs are given together through a peripheral IV (in patients randomized to receive them). This whole chemotherapy regimen is repeated every 3 weeks until disease progression is noted.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

The one TAMC patient entered had stabilization of his disease with the 4 drug arm for 8 months but then progressed. Nationally 393 patients have been treated. So far, response rates (about 15%) and median survivals (16 months) appear to be the same in both arms. Nationally the original ifosfamide dose had to be decreased due to 6 deaths in 163 patients given the original dose. Deaths were due to infections. Other toxcities were primary transient nausea or vomiting in many patients.

Detail Summary Sheet

Prot No: SWOG 8624(87) Status: Completed

TITLE: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma (1) Comparison of VMCP/VBAP to VAD or VMCPP/VBAPP for Induction; (2) Alpha-2b Interferon or No Therapy for Maintenance; and (3) Alpha-2b Interferon + Dexamethasone for Incomplete or Non-Responders

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC;

Department/Section: Medicine/Hematology-Oncology Service

Key Words: multiple myeloma; Alpha-2b interferon

Funding: FY 89 FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: (1) To compare SWOG's best induction chemotherapy program for myeloma with two other very promising programs; (2) to determine if interferon is a better maintenance program than no treatment; and (3) to determine if interferon plus decadron can salvage patients who do not respond satisfactorily to the above induction programs.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive one of the three induction programs. Those who achieve a response (75% M-protein reduction) will be randomized to receive or not receive interferon. Those not achieving response will be offered the above salvage program.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 0

Two TAMC patients have been entered on this study and one is responding well to therapy (at least a partial remission). The other patient did not respond and is on other treatment. Nationally 458 patients have been treated on the study. The response rates were significantly higher on the newer induction programs (65%) compared with SWOG's prim program (47%) but, so far, survivals are only marginally better (55% vs 45% at 30 months). The treatment in all arms was well tolerated except for 3 deaths due to leucopenia. Longer follow up will be needed for data about the maintenance arms.

Detail Summary Sheet

Prot No: SWOG 8642(87) Status: Completed

TITLE: Recombinant Human Interferon-Gamma for the Adjuvant Treatment of High Risk Malignant Melanoma after Surgical Excision of the Primary Lesion, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: Recombinant Human Interferon-Gamma

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Recombinant Human Interferon-Gamma Decision: Completed

OBJECTIVE: To compare the survival and disease-free survival among patients who are at high risk for recurrence of melanoma following resection of all know disease, and who are randomized to receive recombinant human interferon-gamma adjuvant therapy or no adjuvant therapy.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be randomized to receive or not receive interferon-gamma subcutaneously once a day for 12 months.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study has completed its national accrual of patients with a total of 250 patients. Median follow up is still relatively short (less than 2 years) but 45% of patients have relapsed on the treatment arm compared to 31% on the no treatment arm. Clearly this therapy is not beneficial in the short term. Longer follow up will be needed to determine survival differences. Toxicity on the treatment arm was mild.

Detail Summary Sheet

Prot No: SWOG 8691(89) Status: Ongoing

TITLE: A Randomized Comparison of Deoxycoformycin vs. Alpha Interferon in Previously Untreated Patients with Hairy Cell Leukemia

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

Department/Section: Medicine/Medical Hematology-Oncology Service

Key Words: deoxycoformycin; alpha interferon

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To compare the rates of partial and complete remission and the durations of survival in patients treated with the alpha interferon or deoxycoformycin.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1) alpha interferon subcutaneously three times a week for 6 months and then be reassessed for a second 6 months of treatment or 2) deoxycoformycin IV every 2 weeks until the leukemia is gone.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Nationally, there are no response data available (although we know from other studies the responses will be very high). Of the 325 patients on the study to date, only one died of what might be called drug related toxicity (i.e., infection in this case). Toxicity has otherwise been primarily fevers or nausea or vomiting in a minority of patients.

Detail Summary Sheet

Prot No: SWOG 8692(87) Status: Ongoing

TITLE: Therapy in Premenopausal Women with Advanced, ER-positive or PgR Positive Breast Cancer: Surgical Oophorectomy versus the LH-RH Analog, Zoladex, Phase III Intergroup

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC;
MAJ Luke M. Stapleton, MC;
CPT Scott Martin, MC; LTC Lawrence Sakas, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine the response rate and response duration and survival associated with either medical or surgical castration in advanced breast cancer in premenopausal patients.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive an oophorectomy or receive a monthly SQ injection of zoladex until disease progression. At the time of disease progression patients will be offered the other arm of treatment (for example, zolandex patients will be offered oophorectomy).

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

This study remains open; although, we have no patients enrolled to-date.

Detail Summary Sheet

Prot No: SWOG 8710(89) Status: Ongoing

TITLE: Trial of Cystectomy Alone Versus Neoadjuvant M-VAC plus Cystectomy in Patients with Locally Advanced Bladder Cancer

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; COL Martin Dresner, MC; CPT Scott Martin, MS

Department/Section: Medicine/Medical/Hematology-Oncology Service

Key Words: cystectomy;

Funding: FY 89: FY 89:
Gifts:

Periodic Review Date: Sep 90
Decision: Continue

OBJECTIVE: To compare the survival of patients with locally advanced bladder cancer treated with either cystectomy alone or cystectomy plus chemotherapy with M-VAC (Methotrexate, Vinblastine, Adriamycin and Cisplatin).

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to receive 1) cystectomy alone or 2) 3 cycles of M-VAC chemotherapy and then cystectomy.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

The one TAMC patient enrolled was randomized to the chemotherapy arm and had a good response to chemotherapy. He has had his surgery and is doing well on a recent followup visit. Nationally 93 patients have been entered. The only information available is that toxicity has been very tolerable with the only serious toxicity being transient leucopenia.

Detail Summary Sheet

Prot No: SWOG 8711(89) Status: Ongoing

TITLE: A Study of Reproductive Function in Patients with Testicular Cancer

Principal Investigator: COL Jeffrey L. Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC;
LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC;
COL Martin L. Dresner, MC; MAJ Marianne Young, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: testicular cancer;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To evaluate the natural history of seminal fluid and hormone parameters in patients with testicular cancer after orchiotomy and after other treatments such as retroperitoneal node dissection, chemotherapy, and radiation therapy.

TECHNICAL APPROACH: Patients agreeing to participate will have semen analysis beginning after orchiotomy and these will occur every 3 months for 3 years then every 6 months out to 5 years. Testosterone and FSH blood levels will also be done but only half as often as the semen analysis.

PROGRESS: No. of Subjects Enrolled - To Date: 3 Reporting Period: 1

There are no data available yet on this natural history study.

Detail Summary Sheet

Prot No: SWOG 8736(88) Status: Ongoing

TITLE: Treatment of Localized Non-Hodgkin's Lymphoma: Comparison of Chemotherapy (CHOP) to Chemotherapy Plus Radiation Therapy

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: Non-Hodgkin's Lymphoma;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To compare the survival rates and toxicity of two curative approaches in patients with localized (stage I & II), intermediate or high grade non-Hodgkin's lymphoma.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be randomized to receive either 1) 8 cycles of chemotherapy (CHOP) or 2) 3 cycles of CHOP and then 4000 rads of radiation to the involved area.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study opened recently after some administrative delays. There are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8738(88) Status: Completed

TITLE: Treatment of Extensive Non-Small Cell Lung Cancer: Standard Dose Cisplatin vs High-Dose Cisplatin in Hypertonic Saline Alone vs High-Dose Cisplatin/Mitomycin-C

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: cisplatin;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To compare standard dose Cisplatin chemotherapy to high-dose Cisplatin alone and to high-dose Cisplatin plus Mitoymycin-C in a randomized study with attention to response rate, response duration and survival in metastatic non-small cell lung cancer.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to 1) 8 cycles of standard dose Cisplatin (50mg/M^2 Day 1 and 8) or 2) 4 cycles of high-dose Cisplatin (100mg/M^2 Day 1 and 8) or 3) 4 cycles of high-dose Cisplatin (as above) plus Mitomycin-C.

PROGRESS: No. of Subjects Enrolled - To Date: 4 Reporting Period: 1

Of the four TAMC patients treated to date, two have had partial remissions and two had no response. There were 316 patients on the study nationally. The response rate on the arm with high-dose cisplatin plus mitomycin-C was higher (23%) than the other two arms (with about an 11% response rate each). However, the median survivals in the three arms were the same (6 months). Toxicity was primarily vomiting and leucopenia, but three patients died due to cardiac events seemingly related to high-dose cisplatin in each case.

Detail Summary Sheet

Prot No: SWOG 8789(89) Status: Ongoing

TITLE: A Randomized Study of Etoposide + Cisplatin and Etoposide + Carboplatin (CBDCA) in the Management of Good Risk Patients with Advanced Germ Cell Tumors

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: etoposide; cisplatin; carboplatin (CBDCA);

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine the differences in response rate, time to relapse and survival between two active chemotherapy regimens, VP-16 plus Cisplatin and VP-16 plus Carboplatin for good risk patients with germ cell tumors.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive either 1) VP-16 plus Cisplatin IV every 3 weeks for 4 cycles or 2) VP-16 plus Carboplatin IV every 4 weeks for 4 cycles.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

The one Tripler patient was randomized to cisplatin and VP-16 and has gone into a complete remission and has finished treatment.

Detail Summary Sheet

Prot No: SWOG 8791(89) Status: Ongoing

TITLE: Adjuvant Trial of Soft Tissue Sarcoma, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; LTC Y-T Margaret Lee, MC; MAJ Luke M. Stapleton, MC; MAJ Marianne M. Young, MC; CPT Scott Martin, MS

Department/Section: Medicine/Medical Hematology-Oncology Service

Key Words: adriamycin; ifosfamide; mesna

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: Patients who have a high grade (Grade III) soft tissue sarcoma completely removed surgically have about a 25% 5-year survival. This study seeks to improve this statistic.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive either 1)chemotherapy with Adriamycin, DTIC, Ifosfamide and Mesna given continuously IV over 4 days in the hospital every 3 weeks for 6 cycles or 2) no treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study opened recently and there are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8792(87) Status: Terminated

TITLE: Phase III Study of Alfa-n1 (Wellferon) as Adjuvant Treatment for Resectable Renal Cell Carcinoma

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

Department/Section: Medicine/Medical Hematology-Oncology Service

Key Words: interferon alfa-n1;

Funding: FY 88: FY 89: Periodic Review Date: Sep 90
Gifts: None Decision: Terminated

OBJECTIVE: To determine the effectiveness of interferon alfa-n1 in prolonging time to recurrence and patient survival after resection of renal cell carcinoma.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive interferon alfa-n1 IM daily for 5 days every 3 weeks for 12 cycles (36 weeks total) or be randomized to observation alone.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period:

The one TAMC patient entered on this trial had a lot of flu-like symptoms and elected to stop treatment after the first cycle. His symptoms were short-lived but unacceptable to him. Nationally, this study was just terminated due to excessive toxicity. Details of this are expected to be released soon.

Detail Summary Sheet

Prot No: SWOG 8793(88) Status: Ongoing

TITLE: Randomized Phase III Evaluation of Hormonal Therapy vs. Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy

Principal Investigator: COL Jeffrey L. Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: hormonal therapy; pelvic lymphadenectomy; radical prostatectomy

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To compare the time to progression and the survival time for patients with resected stage D1 (positive lymph nodes) prostate cancer when they receive immediate hormone therapy vs. hormone therapy when the disease progresses.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be assigned to receive hormone therapy or observation. If they are assigned to the hormone therapy arm, the patient may choose either orchiectomy or zoladex (a hormone which given qmor SQ produces castrate testosterone levels and has no serious side effects).

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study is ongoing. No data are available yet.

Detail Summary Sheet

Prot No: SWOG 8794(89) Status: Ongoing

TITLE: Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC;
LTC Lawrence Sakas, MC; COL Martin L. Dresner, MC;
MAJ Luke M. Stapleton, MS;
MAJ Marianne M. Young, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: prostate carcinoma;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To compare in a randomized study the disease-free survival and overall survival of patients with completely resected Stage C prostate carcinoma (tumor through capsule or into seminal vesicles) given or not given adjuvant radiation therapy.

TECHNICAL APPROACH: Patients agreeing to participate in this study will be assigned to receive or not receive 6400 rads of radiation to the prostate bed.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study is ongoing; there is no data available yet.

Detail Summary Sheet

Prot No: SWOG 8795(89) Status: Ongoing

TITLE: Randomized Prospective Comparison of Bacillus Calmette-Guerin (BCG) and Mitomycin-C Therapy and Prophylaxis in Superficial Transitional Cell Carcinoma of the Bladder with DNA Flow Cytometric Analysis, Phase III

Principal Investigator: COL Jeffrey L. Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; COL Martin L. Dresner, MC; CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: bacillus calmette-guerin (BCG); mitomycin-C;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To compare the efficacy of Bacillus Calmette-Guerin (BCG) in preventing recurrence of superficial transitional cell carcinoma of the bladder with that of mitomycin-C.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive BCG intravesically weekly for 6 weeks then, beginning on week 8, monthly for 11 more treatments, or to receive mitomycin-C intravesically on the same schedule.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study is ongoing and there is no data available yet.

Detail Summary Sheet

Prot No: SWOG 8804(88) Status: Completed

TITLE: Evaluation of Cis-platinum and DTIC in Inoperable Stage III and Stage IV Melanoma

Principal Investigator: COL Jeffrey L. Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: cis-platinum; DTIC; advanced melanoma;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Completed

OBJECTIVE: To determine the response rate and efficacy of DTIC plus Cis-platinum in inoperable advanced melanoma.

TECHNICAL APPROACH: Patients agreeing to participate will receive DTIC and Cis-platinum IV day 1 every 3 weeks until progressive disease is noted.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Results that are expected to be published soon showed that five out of 53 patients (about 10%) had a response to this treatment. These responses were all partial responses (i.e., more than 50% but less than 100% tumor shrinkage) and they lasted for an average of two months. Twenty-four percent of patients had significant leucopenia but this was transient, and there were no deaths due to toxicity on the study.

Detail Summary Sheet

Prot No: SWOG 8805(88) Status: Ongoing

TITLE: Neoadjuvant Cisplatin and VP-16 Plus Concurrent Chest and Brain Irradiation for Patients with Stage III Non-Small Cell Lung Carcinoma

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS; MAJ Marianne M. Young, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: Cisplatin; VP-16;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To assess the response rate, resectability rate and, ultimately, survival in patients with locally advanced non-small cell lung cancer treated with simultaneous chemotherapy and radiation prior to assessment for possible surgery. The benefit of prophylactic cranial radiation will also be examined.

TECHNICAL APPROACH: Patients agreeing to participate will all receive 2 cycles of Cisplatin and VP_16 plus simultaneous chest and cranial radiation therapy. If they are then considered resectable, they will then have a thoracotomy with resection.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

The one TAMC patient entered on this study so far has done extremely well with all of his tumor (except one microscopic focus) disappearing after chemotherapy and radiation. He is doing well off all treatment. Nationally, there are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8809(89) Status: Ongoing

TITLE: A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy with ProMACE-MOPP (Day 1-8) in Patients with Low Grade Malignant Lymphomas

Principal Investigator: COL Jeffrey L. Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; MAJ Marianne M. Young, MC; CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: ProMACE-MOPP;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine the response rate and survival of low grade lymphoma patients treated with ProMACE-MOPP. Also to compare the disease-free survival in these patients who receive alpha interferon after chemotherapy compared to those who receive only the chemotherapy.

TECHNICAL APPROACH: Patients agreeing to participate will receive 6 cycles of ProMACE-MOPP (followed by limited field radiation if complete remission is not achieved with the ProMACE-MOPP) and then be randomized to receive or not receive low dose alpha interferon 3 times a week subcutaneously for 2 years.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

The one Tripler patient did very well with the chemotherapy and is now in a complete remission. He was just randomized to receive the interferon.

Detail Summary Sheet

Prot No: SWOG 8810(88) Status: Ongoing

TITLE: Six Courses of 5-FU and Cis-platinum with Correlation of Clinical and Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinomas of the Head and Neck, Phase II

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC: CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: squamous cell carcinomas;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if 6 cycles of Cis-platinum plus 5-FU will result in more complete remissions of locally advanced head and neck cancer than 3 cycles.

TECHNICAL APPROACH: Patients agreeing to participate will all receive 3 cycles of Cis-platinum plus 5-FU. Patient who then achieve at least a partial remission (50% or more tumor shrinkage) will get 3 additional cycles. With less than partial, come off study.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study has opened recently. There are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8812(89) Status: Ongoing

TITLE: Treatment of Limited Small Cell Lung Cancer with Concurrent Chemotherapy, Radiotherapy, with or without GM-CSF and Subsequent Randomization to Maintenance Interferon or No Maintenance

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC
MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS;
LTC Lawrence Sakas, MC; MAJ Marianne M. Young, MC

Department/Section: Medicine/Medical Hematology-Oncology Service

Key Words: GM-CSF

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if alpha interferon given after induction chemotherapy and radiation prolongs survival in patients with limited small cell lung cancer. Also this study seeks to determine if GM-CSF will ameliorate the myelosuppression that occurs during induction therapy.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to either receive or not receive maintenance interferon 3 times a week SQ for 2 years after 6 cycles of chemotherapy with radiation with or without GM-CSF.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study opened recently and there are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8857(89) Status: Ongoing

TITLE: Alterrating Cisplatin/VP-16 with Continuous CAV adn Consolidation Chemotherapy for Extensive Small Cell Lung Cancer with PCI for Complete Responders

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC;
MAJ Luke M. Stapleton, MC; CPT Scott Martin, MC;
LTC Lawrence Sakas, MC; MAJ Marianne Young, MC

Department/Section: Medicine/Hematology-Oncolocy Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine the response rate and survival in patients with small cell lung cancer given a new chemotherapy regimen which uses standard drugs but at higher doses.

TECHNICAL APPROACH: Patients agreeing to participate in the study will all receive cytoxan, adriamycin and vincristine alternating with cisplatin/VP-16 at 4 week intervals. After 16 weeks (i.e., 4 cycles) the patients will be restaged. Patients with no tumor then will receive one more cycle of each regimen (i.e., 6 cycles total) and get prophylactic brain radiation.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

This study is ongoing. No patients have been enrolled in this study to-date.

Detail Summary Sheet

Prot No: SWOG 8892(89) Status: Ongoing

TITLE: A Study of Radiotherpy with and without Concurrent Cisplatin in Patients with Nasopharyngeal Cancer, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: nasopharyngeal cancer;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To compare the complete response rate and survival of patients with Stage III of IV Nasopharyngeal cancer treated with definitive radiation versus those treated with definitive radiation plus Cisplatin.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive either 1) radiation (7,000 rads over 7 weeks) or 2) the same radiation plus 3 doses of concurrent Cisplatin (at 3 week intervals).

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study opened recently and there are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8894(89) Status: Ongoing

TITLE: A Comparison of Bilateral Orchiectomy With or Without Flutamide for the Treatment of Patients with Histologically Confirmed Stage D2 Prostate Cancer

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Medical Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To compare the survival of patients with metastatic (ie.D2) prostate cancer who undergo 1) a bilateral orchiectomy plus take a placebo or 2) a bilateral orchiectomy plus flutamide (an anti-androgen).

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to undergo 1) a bilateral orchiectomy and take placebo or 2) a bilateral orchiectomy and take flutamide.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

This study opened recently and there are no data available. The one Tripler patient has had disappearance of all his bone pain.

Detail Summary Sheet

Prot No: SWOG 8896(90) Status: Ongoing

TITLE: Protocol for Surgical Adjuvant Therapy of Rectal Carcinoma: A Controlled Evaluation of a) Protracted Infusion 5-FU as a Radiation Enhancer and b) 5-FU Plus Methyl-CCNU Chemotherapy

Principal Investigator: COL Jeffrey Berenberg
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words: rectal carcinoma

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To compare the recurrence rates and survival in patients having potentially curative resections of Astler-Coller Stage B2 and C rectal cancer treated with sequential chemotherapy and radiation therapy using 5-FU as a radiation enhancer given either by simple IV bolus or by protracted venous infusion concomitant with radiation therapy.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized post-op to receive either 1) 2 5-day cycles of 5-FU 5 weeks apart and then radiation therapy to the pelvis beginning on day 64. Three days of 5-FU will also be given on the first and 5th week of radiation. Finally, 5-FU will be given again for 2 5-day cycles beginning 28 days after radiation is completed or 2) the same treatment as #1 but with constant IV infusion 5-FU during all of radiation therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

New start.

Detail Summary Sheet

Prot No: SWOG 8899(88) Status: Ongoing

TITLE: A Prospectively Randomized Trial of Low-Dose Leucovorin Plus 5-FU, High-Dose Leucovorin Plus 5-FU, or Observation Following Curative Resection in Selected Patients with Duke's B2 or C Colon Cancer

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: leucovorin;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine if surgery plus either 5-FU and low dose Leucovorin or 5-FU and high dose Leucovorin will result in improved survival over surgery alone in resected Dukes's B2 and C colon cancer.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized post-operatively to receive 1) 5-FU plus low dose Leucovorin IV push Day 1-5 q4-5 weeks x 6 cycles, or 2) 5-FU plus high dose Leucovorin IV over 2 hours weekly for 6 of each 8 weeks for 24 doses, or 3) no chemotherapy.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

The one TAMC entered on this study was randomized to no chemotherapy and is presently doing well. This study is still open but has been just changed with deletion of the "no chemotherapy" arm and addition of two other arms (one with 5-FU plus levamisole and another with 5-FU plus levamisole plus lencovorin). These changes occurred out of the results of a large intergroup study showing better survival in these patients given 5-FU plus levamisole or leucoverin versus patients given no treatment.

Detail Summary Sheet

Prot No: SWOG 8900(89) Status: Ongoing

TITLE: Randomization Trial for VAD and VAD/Verapamil for Refractory Multiple Myeloma

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: LTC William J. Uphouse, MC;
MAJ Luke M. Stapleton, MC;
CPT Scott Martin, MS; LTC Lawrence Sakas, MC

Department/Section: Medicine/Medical Hematology-Oncology Service

Key Words: vincristine; adriamycin; dexamethasone; verapamil;

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: None Decision: Continue

OBJECTIVE: To determine the response rate and response duration to chemotherapy alone (VAD) and to chemotherapy (VAD) plus Verapamil in multiple myeloma patients who have failed previous chemotherapy.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive VAD given as a 4 day IV infusion or to receive the same VAD plus p.o. Verapamil.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study recently opened and there are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8905(89) Status: Ongoing

TITLE: Phase II/III Study of Fluorouracil (5-FU) and Its Modulation in Advanced Colorectal Cancer

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine and compare the response rates of 5-fluorouracil given by different schedules and/or with biochemical modulators to patients with advanced colorectal cancer.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 5-FU by one of seven schedules. Those schedules involve infusional or IV push 5-FU with or without leucovorin or PALA.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study just opened and there are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8906(90) Status: Ongoing

TITLE: Evaluation of Merbarone in Hepatoma, Phase II

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words: hepatoma

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To evaluate the response rate and response duration of advanced hepatomas treated with merbarone.

TECHNICAL APPROACH: Patients agreeing to participate will all receive merbarone by continuous IV infusion for 5 days with these cycles repeated every 3 weeks until the patient shows tumor progression. A central line (Hickman or Port-a-cath) is placed for these infusions.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

New start.

Detail Summary Sheet

Prot No: SWOG 8912(89) Status: Ongoing

TITLE: Evaluation of Fazarabine in Patients with Recurrent Squamous Cell Carcinoma of the Head and Neck

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine the efficacy of Fazarabine in the treatment of recurrent head and neck cancer.

TECHNICAL APPROACH: Patients agreeing to participate will receive fazarabine IV over 45 minutes for 5 days every 4 weeks.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

This study remains open and no data is available yet. The one TAMC patient tolerated treatment fairly well but had only a minor response.

Detail Summary Sheet

Prot No: SWOG 8917(90) Status: Ongoing

TITLE: 5-Fluorouracil, Leucovorin and Roferon-A in Advanced Colorectal Cancer, Phase II

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine the response rate of advanced colorectal cancer to a combination of 5-fluorouracil, leucovorin and Roferon-A (interferon).

TECHNICAL APPROACH: Patients agreeing to participate will all receive 5-fluorouracil plus leucovorin IV push daily for 5 days every 4 weeks for 2 cycles then every 5 weeks thereafter. Simultaneously they will receive interferon (Roferon-A) subcutaneously three times each week.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study just opened and there are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8939(90) Status: Ongoing

TITLE: Evaluation of Merbarone in Colorectal Cancer, Phase II

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words: colorectal cancer

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To evaluate the response rate and response duration in patients with metastatic colorectal carcinoma treated with merbarone.

TECHNICAL APPROACH: Patients agreeing to participate will all receive merbarone by continuous IV infusion for 5 days with these cycles repeated every 3 weeks until the patient shows progression of the tumor. A central line (i.e., Hickman or Port-a-cath) is placed for these infusions.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

New start.

Detail Summary Sheet

Prot No: SWOG 8940 (90) Status: Ongoing

TITLE: A Phase I Study of the Combination of Recombinant Human Interleukin 1-Beta, Etoposide and Carboplatin in Patients with Metastic Cancer

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine the maximum tolerated dose of recombinant human interleukin 1-beta in cancer patients receiving the combination of carboplatin and etoposide and to determine the tumor response to this 3 drug combination.

TECHNICAL APPROACH: Patients agreeing to participate will all receive monthly cycles of carboplatin (day 1) IV and etoposide (day 1, 2, 3) IV plus recombinant human interleukin 1-beta (given IV for 5 days starting on either the first or fifth day of chemotherapy). The first chemotherapy cycle, however, will not include the interleukin.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

This study opened very recently and the one TAMC patient is beginning treatment. No other data are available.

Detail Summary Sheet

Prot No: SWOG 8952(90) Status: Ongoing

TITLE: Treatment of Advanced Hodgkin's Disease - A Randomized Phase III Study Comparing ABVD vs MOPP/ABV Hybrid

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To compare ABVD to the MOPP/ABV hybrid as therapy for patients with advanced Hodgkin's disease in terms of complete response rates, survival and toxicities.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1) MOPP/ABV every 28 days for 8 cycles or 2) ABVD every 28 days for 8 cycles.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

This study just opened and there are no data available yet. The one TAMC patient has started therapy and already appears to be heading toward remission.

Detail Summary Sheet

Prot No: SWOG 8957(90) Status: Ongoing

TITLE: Feasibility Trial of Post-Operative Radiotherapy + Cisplatin Followed by Three Courses of 5-FU + Cisplatin in Patients with Resected Head and Neck Cancer, Phase II

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To evaluate the feasibility of administering 3 courses of chemotherapy to resected head and neck cancer patients who have received cisplatin and radiation post-operatively.

TECHNICAL APPROACH: Patients agreeing to participate will all receive cisplatin once every 3 weeks for 3 doses during post-operative radiation therapy and then receive cisplatin plus 5-FU every 3 weeks for 3 doses after radiation therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

New start.

Detail Summary Sheet

Prot No: SWOG 8997(89) Status: Ongoing

TITLE: Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer with Cisplatin Plus Etoposide with Either Bleomycin or Ifosfamide

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words:

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To determine the response and duration of remission with cisplatin, etoposide and bleomycin versus cisplatin, etoposide and ifosfamide.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized one of the above 2 programs and receive 4 cycles of that program every 3 weeks.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study just opened and there are no data available yet.

Detail Summary Sheet

Prot No: SWOG 9013(90) Status: Ongoing

TITLE: A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Local Regional Disease, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators:

Department/Section: Medicine/Hematology-Oncology Service

Key Words: esophagus; squamous carcinoma

Funding: FY 89: FY 90: Periodic Review Date: Sep 90
Gifts: Decision: Continue

OBJECTIVE: To compare the relapse rate and survival in patients with local regional esophageal cancer treated with surgery alone versus pre-op and post-op chemotherapy plus surgery.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive surgery alone or to receive 3 cycles of Cisplatin plus 5-FU then surgery, then 2 further cycles of Cisplatin plus 5-FU.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

New start.

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